FTC Workshop: The Contact Lens Rule and the Evolving Contact Lens Marketplace
March 7, 2018
Segment 3
Transcript

BETH DELANEY: OK. So with that, I want to just point out that we do have someone that will be walking around and collecting questions. That's Courtney and she's sitting over in this corner over here. So she'll get up every once in a while and kind of wander around. Just hold up your card, if you have one. And she'll collect that and bring it over to Rich who will then deliver them to me. And hopefully we'll have some time to answer questions. But as Alyssa said, if not, we're certainly looking at all of them. And we'll incorporate those issues into the rule making record.

So what I'm going to start with is we're going to talk about the verification process. And as you all know, the Fairness To Content Lens Consumers Act and the rule set forth the conditions under which contact lenses are sold. And more specifically, a seller may sell contact lenses only in accordance with a prescription that is either presented directly to the seller or verified by direct communication.

The direct communication means that a prescription is verified if the prescriber confirms that the prescription is accurate by getting right back to the seller. The prescriber informs the seller that the prescription is inaccurate and provides the accurate information. Or the prescriber fails to communicate with the seller within eight business hours after receiving the verification request. So with that statutory framework in mind, the goal of this afternoon's panel is to examine the verification process from the perspective of the prescriber, the seller, and the consumer. And what we want to do is we want to explore what's working with verification, what isn't, and we want to use our time today to brainstorm to improve the process to make sure that consumers are getting the contact lenses that have been prescribed for them. So we have a great panel here today. I'm looking forward to a very informative and interactive discussion. And Paul's going to introduce our panelists.

PAUL SPELLMAN: Hi. I'm Paul Spellman. And, as you know there are longer bios in the handouts outside. But I'll just give brief bios of the panelists we have with us today in no particular order. Cindy Williams is the general counsel of 1800CONTACTS. As such, she advocates on behalf of contact lens consumers and is responsible for managing legal and legislative affairs for 1-800 which was, as you know, one of the first and still the most prominent telephone and online sellers of contact lenses.

Jennifer Summer is the director US Ethics and compliance at Walmart. For the past eight years she has overseen the optical practice compliance program for all Walmart Vision Centers and Sam's Club Optical stores in 47 states and Puerto Rico. Dr. Tim Steinemann is a professor of Ophthalmology at Case Western Reserve University in Cleveland, Ohio. He also sees patients at the MetroHealth Medical Center Hospital in Cleveland and at University Ophthalmology Associates, an eight-doctor private practice.

David Cockrell is an optometrist who has a practice with his wife, who's also an optometrist, in Stillwater, Oklahoma. Dr. Cockrell is the past president of the AOA and has testified before

various state and federal legislatures about contact lenses and eye health. And Shaun Schooley is the Vice President of Global Marketing Technology at CooperVision. He's responsible for CooperVision's global marketing initiatives including technology development, e-commerce, and the subsidiary EyeCare Prime, which operates the contact lens subscription LensFerry. And with that, I'll hand it over to Beth.

BETH DELANEY: Great. So to get some background information, we're going to start with an overview of the verification process from the seller's perspective. So Cindy, could you give us an overview of how 1-800 processes verification requests?

CINDY WILLIAMS: Yeah, sure thanks, Beth. I'm glad for the chance to talk about our verification system. It's something that we are very proud of as a company. 1-800 processes close to 3.6 million orders every year. And we take our compliance obligations very seriously. We have made significant investments in developing efficient systems and protocols that allow us to ensure that for every order, we either have the customer's prescription or we properly verify the order.

Today we have current prescriptions on file for about 40% of orders. We would like to process more orders with a prescription. With a prescription, the consumer gets their lenses faster. And they are often on their last pair, which is evidenced by our data showing that 32% of our customers pay for expedited shipping. But prescribers don't always release. We've talked about that in earlier panels. And some consumers may not have their prescription handy when they place an order.

So we need to verify to serve our customers. That's not going to go away. So to handle verifications, we use a system called HIVR, which stands for human initiated voice response. We don't consider this to be an automated system. Every call is initiated by a live customer service agent who confirms that the call was received by the right person, or the right offense. So, for example, if we are trying to reach Sears Optical, our live customer service agent confirms that the call is actually answered by Sears Optical.

We use a recorded voice to convey the information. Because it is likely to be more accurate and be more reliable. The length of our call varies, depending on whether it's answered live or if the information is left on an answering machine. But in both cases, it's just about two minutes. HIVR is the gold standard for CLR compliance certification. It conveys information accurately and in an understandable fashion with minimal burden on prescribers and allows us to document our compliance efficiently.

Our records show that, on average, prescribers are asked to verify just one order a week from 1800CONTACTS. Prescribers are not always cooperative. They often hang up on our calls, rather than taking advantage of the option to hold or have our system call them back later. We would like prescribers to understand that while the call was coming from 1-800, it's their patient who is asking for them to take two minutes to verify their prescription.

We are acting as their patient's agent, just like a pharmacy might call on a patient's behalf. After the call is placed, if the prescriber or tells us that the customer is not their patient, or the

prescription has expired, we cancel the order every time. We think the current verification system works well for consumers. Our data indicates that the error rate, under the current system, is relatively low. And the contact lens wearers are getting exams on a regular basis within the AOAs own guidelines, which, as we heard earlier today, are more restrictive than what the AAO recommends.

In less than 30 seconds, let me give you some facts. Our survey evidence shows that the majority of contact lens wearers have an exam about once every 12 to 16 months. And that is consistent with the Johnson & Johnson survey that was submitted in the rule making.

BETH DELANEY: OK. So this is going to be quick?

CINDY WILLIAMS: Yes.

BETH DELANEY: Because I want to get back to verification and--

CINDY WILLIAMS: OK, absolutely.

BETH DELANEY: Focus on that.

CINDY WILLIAMS: So I won't go into any more. I was just going to talk about exam frequency. But the one other thing I wanted to mention, Beth, is that our data shows that consumers are, we talked about expired prescriptions and buying lenses. Our data shows that about 10% of consumers are able to purchase lenses with an expired script. And importantly, that number does not vary across channels. So about 10% of consumers report buying lenses with an expired prescription regardless of whether they purchase from an independent retailer, like a Big Box store, an online provider like 1-800, or their own ECPs office.

BETH DELANEY: OK. So we'll get more into expired prescriptions with Dr. Steinemann. And you'll have a chance to talk more about that but I did want to just get this information from you. So 40% of your orders are made with a copy of the prescription?

CINDY WILLIAMS: Yes.

BETH DELANEY: OK.

CINDY WILLIAMS: It's either on file when the customer orders, Beth. Or it is provided during the ordering process.

BETH DELANEY: OK. And do you have any sense of what percentage of verification requests are corrected by a prescriber?

CINDY WILLIAMS: You know, we didn't track that. I know you asked us. But what we know is that, of the 60% that are going to verification, right, some are corrected. As you said, some are approved by doctors. And sometimes we get a prescription in from a doctor during that process.

And it's fair to say that of those that go to verification, the majority are passively verified. And we're going to try to get you more specifics in our comments.

BETH DELANEY: OK. That's great. So let's turn to Jennifer who also has some interesting information about a different way to verify prescriptions.

JENNIFER SUMMER: Thanks Beth. So I'll be speaking on behalf of our retail locations. We have approximately 2,800 Walmart Vision Centers and 500 Sam's Club Opticals across the country in 47 states. And in 46 of those states, we actually sell the contact lenses. That's about 3,300 locations. We have probably 3,500 to 3,700 doctors who co-locate with us. And as you probably remember from Wally's presentation, there's three different models. The vast majority of our model is actually a sublease or a license agreement with those doctors.

So in response to your question, Beth, about our verification process, we actually have a corporate policy that says that if a customer or a patient comes into the vision center or the optical and wants to purchase contact lenses and they don't have a prescription in hand, then we have a form that our opticians are required to complete. And it has all of the necessary information that would be relevant for that verification process.

Those opticians then will contact the prescriber's office to make sure they have the correct fax number. And they'll actually fax that form over to the prescriber's office. If the prescriber doesn't respond in some form or fashion to say that that prescription is invalid, or it's incorrect, then the opticians will dispense. Now that being said, we did an informal survey across our vision center managers. It was a proxy 40 vision center managers in 15 states that responded in relation to this workshop.

And they found that the verification process that we have doesn't serve their patients in the way that they want. So we're really proud of our optician's for taking care of their patients. What they actually do is they'll call the prescribers office while the patient is there in the vision center and obtain a copy of the prescription. They find that that's more effective. They can ensure that there's an a valid prescription and that they have all of the parameters needed to fill the order.

And so our verification process is actually extremely low for our stores in that we probably verify less than 10% of our prescriptions, just because our optician's are actually calling the prescriber's office. When we probed a little more and said, well, how long does it take to get a copy of the prescription? We're very pleased to hear that it's within 15 to 30 minutes if the doctor's office is open.

And so they can take care of that patient while they're in the vision center in a very short amount of time. And they can either walk away with their order or have it shipped to their home according to their preference.

BETH DELANEY: Can I also interrupt for a second? So, do you get the prescription back by fax?

JENNIFER SUMMER: Correct.

BETH DELANEY: And faxes are still being used?

JENNIFER SUMMER: Yes. I'll give you a little content--

BETH DELANEY: Let me get this on the record that faxes are still being used.

JENNIFER SUMMER: Let me give you some context for that. So it has been just recently that, obviously, our vision centers are in a larger part of our store. We're a mass merchandiser. And it's been recently that we've actually opened it up to where our hourly associates can receive attachments via email. And that didn't have anything to do with the vision center itself. But obviously, we have a number of hourly associates in a typical super center.

And so we didn't want them to receive attachments. That would inhibit the ability to receive a prescription via email. We've also found it's more secure, especially with the prevalence of privacy concerns and data security concerns. And Walmart being a very large corporation, we found that fax is much more efficient. It's the same process that we use in our pharmacies. So we have approximately 5,000 pharmacies across the country. And so we still do use fax, which makes it better for our patients. Because we know that their data is being secured during that transmission.

BETH DELANEY: So then, just to close the loop on Walmart, I know you also sell online. And could you just briefly tell us how that process works? I think it diverges a little bit from your in-store process.

JENNIFER SUMMER: Absolutely. So we have two websites that we operate, one for the Walmart brand and one for the Sam's Club brand that sells contact lenses online. That's a partnership that we have with a third party that actually operates those sites for us. And so their verification process is when the patient doesn't have a prescription that they can upload or text or email back to the company that they will actively call the prescriber's office.

About 80% of the verifications occur. The company is looking into how they can make it easier for patients to get their prescription to the company so that they can lower that verification number. But they've had pretty good success with verifications.

BETH DELANEY: So that would then be active verification, because they're calling and they're actively verifying?

JENNIFER SUMMER: Yes.

BETH DELANEY: OK. So not much passive verification at Walmart.

JENNIFER SUMMER: No, it's actually pretty low.

BETH DELANEY: OK. Great. So what I'm going to do now is just ask both of you kind of a follow up question. So what I'm wondering is, from a business standpoint, does it matter to-- I

mean, you've kind of almost answered this. You would like to get the copy of the prescription. That's ideal.

CINDY WILLIAMS: Absolutely.

BETH DELANEY: OK.

CINDY WILLIAMS: We think the consumer gets their lenses faster. And there's more burden involved for both sides.

BETH DELANEY: OK. And so when you get the copy from-- and the same for Walmart?

JENNIFER SUMMER: Absolutely the same.

BETH DELANEY: OK. So with, just to clarify, so with Walmart, if you get a copy of the prescription, then the inquiry ends there? Or do you still contact the doctor?

JENNIFER SUMMER: No, we actually, once we get a copy of the prescription, if it has all the required elements per state law as well as it's valid, we will go ahead and fulfill the order.

BETH DELANEY: OK, great. And that's both in-store and online?

JENNIFER SUMMER: Yes.

BETH DELANEY: OK, great. So do either of you have suggestions on how to incentivize consumers to give the prescription? Because I think we've heard some data that even if patients have-- that there's a certain percentage of patients that have a copy of their prescription that aren't using it.

JENNIFER SUMMER: So I'll speak from a store's perspective. And I think optician's have done a fantastic job of this. You know, they educate the patient on the value of having that prescription in hand. Because the customers already come to the store to purchase their contact lenses. And if they don't have that prescription in hand, they make sure that the patient understands that there's going to be a time period. And that's not convenient for the patient. And we're all about convenience and making sure that the patient has the best experience.

And so as they're going through that education process, what we've found through our informal survey of our vision center managers is that we actually have a number of patients who will call their prescriber ahead of time before they even come to the store so that they can have that prescription faxed in so that it's not inconvenient for them. Now, if we do have to make that phone call, and again, it's usually 15 to 30 minutes by the time we actually get a copy of the prescription, usually we'll invite the customer to either sit and wait or they can shop in the store.

But again, that's an inconvenience for the patient. So we've undertaken that education effort to make sure that they understand they really need to have that prescription in hand.

BETH DELANEY: Cindy, do you have any anything to add with what 1-800 does to incentivize?

CINDY WILLIAMS: Well, absolutely, Beth. We are always trying to get prescriptions from consumers. And during the ordering process alone, we ask them at the beginning to upload their prescription. If they don't have it at the beginning, we ask them again at the end to upload it. And then as soon as their order is processed, within two minutes, they're getting their order confirmation that they got their lenses.

And we're telling them, if you didn't use prescription this time, please give it to us now for your next order. Because it's going to make it faster for you. So we have also run promotions to get prescriptions from consumers. So, for instance, in May of 2016 and May of 2017, we offered consumers a 10% discount on their next order of contact lenses if they would simply send us in their contact lens prescription.

BETH DELANEY: And did that incentivize consumers? Was there a bump with that?

CINDY WILLIAMS: Yeah. We have seen that these promotions and the regular interaction during the ordering process and reminding them that if their prescription is on file in 10 minutes, we can process their order for shipping. They don't have to wait that extra day for the verification process. And that message really resonates with consumers.

BETH DELANEY: OK, great. Paul, I'm going to let you--

PAUL SPELLMAN: Sure. We've heard a little bit about the seller perspective, so if we could switch to the prescriber perspective with verifications. We could start with Dr. Cockrell. What's your view of the verification framework, how the process is working?

DAVID COCKRELL: Thank you very much, Paul. The verification process, as it stands right now, is ineffective and maybe the politest was to say it is it doesn't work. It's a one-way system. In my particular office, and every office, I'd like to recognize all the members of the AOA that are here from across the country. This is such an important issue for us. We want to make sure our voice is heard. We appreciate that.

Every single doctor in this office gets contacted virtually-- I mean in this building, every single day by some seller with a prescription that's expired. Or maybe it's correct or maybe it's incorrect. When we try to recontact that entity that sent it to us, there is no way to recontact that entity. So it's a one-way issue. I heard reference this morning that one of the companies perceives themself as a pharmacy.

With a pharmacy, if there's any question at all about a medical prescription, when I write that, and these are medical prescriptions as we heard from the FDA and the CDC. When I wrote that medical prescription, if there's any question, I'm able to get a hold of them. I can't get a hold of a reseller. So, no I don't think the verification process works. I think, along with that, for example, we've got a situation where some retailers, for example, Hubble Contact Lenses tells patients online, get back with them within 48 hours.

Well, the rule says, eight hours, right? So it's intentionally misleading to a provider, or a provider's staff if they don't realize it. So there's a variety of problems with it.

PAUL SPELLMAN: Could I just ask you a little bit about how your office handles verification requests typically? Do you handle it or does the staff handle it? And do you have a preference?

DAVID COCKRELL: In our office, our staff handles it. We have five doctors, 32 staff. And so when that verification request comes in, it goes to our contact lens manager. It comes in by fax often. Sometimes it comes in by a robocall, many of which we can't understand. We actually played one for Chairman [INAUDIBLE] last year that came into my office that you couldn't understand. So sometimes they're just not able to understand.

But at any rate, one we figure out who it is, it goes to our contact lens manager. At that point, we make certain that the information goes back within that eight-hour period of time.

PAUL SPELLMAN: Dr. Steinemann if we could switch to you. How does your office handle such requests? And what's your view?

TIM STEINEMANN: So we receive about 5 to 20 of these requests per week across different sites. Most of these requests come in through fax. Some of them come in through calls. And these are not live calls. These are robocalls. Many of those robocalls are unintelligible or cut off. We have no way of responding or even verifying the information. So I agree with Dr. Cockrell, the verification framework is insufficient. It doesn't work. And it's not properly enforced.

In many instances, prescribers receive verification requests that are expired, incorrect, or for a patient that we have no record of. And, in fact, we studied this. And I'll be glad to share that information.

PAUL SPELLMAN: Yeah, if you could. And I should preface this by saying that you conducted basically in an informal survey of your offices.

TIM STEINEMANN: That's correct. I work at MetroHealth Medical Center. I also work at a private office called University Ophthalmology Associates. So we have two very different sites of practice. The MetroHealth site is a community hospital. It is the county hospital of Cleveland. It is a very large busy hospital. We see probably well over 40,000 visits per year. We serve everybody. And so we have a very, very diverse patient population.

We serve many under served people, modest means. On the private side, it's your typical private office. And we see people who are insured. In any case, we looked at verification requests in both sites. What we found, in the MetroHealth office, we found an error rate anywhere from 50% to 60% at the MetroHealth site. At the University Ophthalmology private site, we found about 25% error rate.

So there's a big difference. But it's way too high. I even polled my colleagues at the Cleveland Clinic Cole Eye Institute. I don't work there. But I polled them. And I asked them to look at their site and look at verification requests there. It's about a 30% error rate there.

PAUL SPELLMAN: If I could just interrupt for a second. When you specify error rate, my understanding is that there you've grouped a number of different things.

TIM STEINEMANN: Correct.

PAUL SPELLMAN: Could you explain what those are?

TIM STEINEMANN: So we found four main sources of error. The biggest problem and the biggest offense are expired prescriptions. How big? At MetroHealth probably 40% are expired. At the private office probably 20% are expired. At Cole I Eye Institute probably 30% are expired. The second biggest are patients that we have no record of. These are not our patients who are claiming that I am their doctor. How big is that? 10% to 15%.

The third problem we see are errors in the-- presumably the errors in the transcription of the prescription. The prescription is not accurate. And then the fourth error that we see are people who are either not approved for contact lens fitting, did not complete the fitting process, or do not have a valid prescription, don't have a prescription and are trying to gain one. Let me give you an example. Here is something that we just received at MetroHealth the other day. This came in on Friday, 3:00 A.M.

This patient is a patient of ours. Her last exam was 2015. We have no record at MetroHealth that this patient was ever fit with contact lenses. I know, by the way, this is the third attempt in three weeks to try to gain contact lenses. There's a contact lens prescription listed here. We blocked it.

PAUL SPELLMAN: Well, now some people would say that by blocking it and by noting these incorrect verification requests that the system is working and that you're stopping these incorrect requests. So what do you think we should take away from these recalls?

TIM STEINEMANN: My response to that is see how much time this takes. Does it take one to two minutes? No. It takes probably at least five minutes to do an average request. If there are discrepancies, try 20 or 30 minutes.

BETH DELANEY: OK, well lets--

TIM STEINEMANN: It's a tremendous expense.

BETH DELANEY: Let's talk a little bit about the prescriber preferences for verification requests. Do either of you have a-- what do you think would work better in terms of--

TIM STEINEMANN: Written requests only, no robocalls.

DAVID COCKRELL: On top of that, I think it needs to be a two way street. We need to know that re-- we need to know that whatever it is we sent is received. We need to be able to contact whoever that seller is immediately. Not-- we can't even leave a message on most of them, let alone not be able to contact them. So with no verification, and just as these ones that we reject, like Dr. Steinemann was talking about, yesterday, day before yesterday when I was in my office,

we had three immediately from three different online resellers for the same patient for two different prescriptions, two of the three.

So the patient is clearly shopping to see who will fill it or will miss it. And we have no idea if they got it filled or not. There's absolutely no-- there's no response from the reseller to let us know, we received your rejection. We did not fill his prescription. If we really want to look after patient health care, I think it's important.

I'd like to correct one other thing that I heard this morning. Since she mentioned it earlier. I took moment over lunch to look at what the American Academy of Ophthalmology actually says in terms of contact lens examination.

BETH DELANEY: I joined you, right?

TIM STEINEMANN: Let me speak to that.

BETH DELANEY: OK, OK. You can, OK, Dr. Steinemann, I want it really quick though. Because we need to move on with verification, too.

TIM STEINEMANN: That was quoted out of context, five to 10 years applies to people who are young, under age 40 and have no risk for eye health problem.

BETH DELANEY: OK.

TIM STEINEMANN: Contact lens--

BETH DELANEY: Guidelines--

TIM STEINEMANN: There is always a risk for eye health.

BETH DELANEY: It's not listed in the guidelines. It is in the AOA guidelines. But contact lens use is not listed as a risk factor, I thought, in the--

TIM STEINEMANN: Please look at the preferred practice patterns of the American Academy of Ophthalmology, annual exam, contact lens exam.

BETH DELANEY: OK.

TIM STEINEMANN: Annual exam for contact lens wearers.

BETH DELANEY: OK. So this is a--

TIM STEINEMANN: Please look at the EyeSmart website, annual exam for contact lens wearers.

BETH DELANEY: Well, this is a factual issue that we can clear up. But I did want to have-- we've a little bit more time before we switch over to Shaun. So I have a question. So taking into account the things that we've heard today so far, in terms of what the risk factors are, which are over-wearing your contact lenses, some hygiene issues. If the biggest percentage of problematic verification requests are expired prescriptions, but we also have data that shows that it seems like contact lens consumers are going back fairly frequently, I think from Steve, his data showed that 80% seemed to indicate that they had an exam in the last year.

And if you bump that up to two years, it was 94%. So how do those data points translate into your concern? So, do you know what I'm saying. Like, if people are going back and there is-- maybe somebody is ordering a couple of months at the end of their prescription, is that related to a health risk?

TIM STEINEMANN: Sure.

BETH DELANEY: I mean-- so, yeah.

TIM STEINEMANN: Sure, it's related to a health risk. Why? Because people don't come back. Or they may not know it to come back. And nothing can replace a face-to-face teaching, monitoring, and most importantly supervision. That supervision is stronger and the teaching is stronger through the follow-up contact lens exam. It's not so much the exam, I want to know when the patient comes back, tell me how you take care of your lenses. Are you having any problems?

Now, trust me when I say, I don't fit contact lenses. But I spend a considerable amount of my time taking care of people's contact lens problems.

BETH DELANEY: OK, OK, so let's--

DAVID COCKRELL: Can I address that as well?

BETH DELANEY: Sure, yeah.

DAVID COCKRELL: You know, all of us, every doc in the room sees patients with contact lens problems from minor to serious in patients who come back on time but certainly in patients who don't come back on time. I had a patient within the last month who's been wearing the same daily contact lens for over two years. Now think about that for a second.

BETH DELANEY: Right, I mean, there's--

DAVID COCKRELL: So the reality is there's all these outliers. But as you heard this morning, I've got patients who've also purchased the same sort of contact lenses for four years in a row and never been seen. So there's multiple problems with it. If we get back to the health problems, there as Dr. Steinemann described. We all see them every day.

BETH DELANEY: Right, and part of what this workshop is about is extracting empirical evidence about what's going on. Because it is horrifying, I'm sure, for you to see a patient that has done these things. But we also want to have some hard data on the numbers of people that are going back to the doctor and the actual risk factors and the actual adverse events, how that translates across the whole population of people wearing contact lenses.

TIM STEINEMANN: You know what you know. And all I can say is, from my experience, I'm a clinician. I am a cornea trained specialist. This is what I do when I go to work every day as an ophthalmologist. And ophthalmologists, I think, are in a very unique position to see these sometimes disasters. And that data was presented. You want the data? The data was presented this morning.

BETH DELANEY: OK. So let's--

CINDY WILLIAMS: Can I just respond to the--

BETH DELANEY: Yes, Cindy, jump, yes, yes.

CINDY WILLIAMS: Right. So 1-800 I know that maybe Dr. Steinemann's data was verification calls through fax. But 1-800 does have a 24-hour doctor service line that is toll free that can be used by the doctors at any time if they want to cancel an order. I think it's really important to note here that prescribers have the option to cancel orders placed with an expired prescription by simply responding to those calls. When they do this, we honor it every time.

If they think that buying with an expired prescription presents a serious health risk, then one would expect that they would do that every time for their patients in the best interest of their patient's health.

TIM STEINEMANN: Beth, let me just say one other thing. And that is to change behavior is difficult. And we all talked about in many of these sessions, we've talked about changing behavior. Because they're absolutely right. Why do people get into trouble? It's their behavior, misuse, not a product. This is a medical device and needs to be treated with respect. The patient needs to buy into that. The patient needs to have some skin in the game. We need to be very careful about over-commoditizing this process.

BETH DELANEY: Right. We do need to figure out ways to change behavior. And hopefully we'll get some study evidence. I mean, right now I don't think we have evidence that shows that annual exams are the be-all and end-all yet.

DAVID COCKRELL: It's going to be difficult to get that. But I will tell you that I didn't come to this meeting expecting to be surprised by anything I heard. I was surprised. So for at the last panel that completely disregarded patient health when it came to filling prescriptions and the attempt to apply that all contact lenses fit the same were that virtually all patients can wear one or two lenses. That's just not true.

BETH DELANEY: OK, well--

DAVID COCKRELL: I want to make one more comment.

BETH DELANEY: I know. What I do want to reiterate is we have a comment process that's open for another month. And we want to hear. We want all these issues that are raised. We want you to go home, write up your rebuttal to it, and send it in. Because we have 4,000 comments. I read all 4,000. I did group the form letters together. But we did look at all of them. So let's switch gears a little bit. And we'll enjoy the next presentation from Shaun. We're going to talk about CooperVision's LensFerry product and how that product works and how prescription verification works.

SHAUN SCHOOLEY: Thanks Beth. So LensFerry is a contact lens reorder system that allows a prescriber, an ECP, to offer their patients a really convenient email, web, and mobile reorder capability. LensFerry works by drawing the data out of the practice management system, or the EHR, and then sinking it over to LensFerry. That allows a patient to be able to access an active and validated Rx their future purchase. So they don't need to actually go through a verification process when they make a re-purchase through the LensFerry product.

Some of the obvious benefits of that are, this is a vast simplification for the prescriber. And then for it really opens up for the patient an incredibly convenient and simple way for them to be able to access products through the way that they like to purchase today.

PAUL SPELLMAN: Right.

SHAUN SCHOOLEY: Through pretty much any channel.

BETH DELANEY: So how does how does LensFerry compete with other retailers? I mean, in terms of price, like if somebody is at the optometrist, they might pull out their phone and price contact lenses right there. How does-- is it just the convenience that makes it?

SHAUN SCHOOLEY: It's really not. And I guess, I sat through this morning as well. And I've heard these comments. And I'm lucky in my job. I get to spend a lot of time out in the field. We work with over 5,000 offices globally in the direct patient space. And I spend a lot of time watching behaviors in the office and what this process is that they go through for verification and for validation.

The things that I see happening are, the commonalities are, that consumers are probably more empowered now than they've ever been, as far as being able to shop and buy. And it is very true. I think if we all stepped away from our desk job here today and thought about how we buy and how we interact, we've all got a computer in our hand essentially at this point. It's a fundamentally different world that we live in today then I think when we looked at from 2004 even.

And because of that, like you're saying, Beth, there's a lot of transparency of price. And because of transparency of price, my experience at least is that doctors are very aggressively setting-- prescribers are very aggressively setting price. And they often are benchmarking it off of the

online retailers. Because they know the consumer can open their phone standing there in the office and find the same exact product available or for a stated price online.

So LensFerry allows a doctor to set their own price. We don't dictate price through LensFerry. And then the doctor, what we do find, is the doctor is often benchmarking that off of the industry standards that are out there. And there are additional features and capabilities in there for negotiations or other set pricing or price matching or other things like that for specials and that sort of thing. It opens up a convenient way for the patient to be able to access products from their prescriber without having to go through some of the steps that they might have to go through otherwise.

BETH DELANEY: So we're going to hear more about another subscription model later in the day. But so LensFerry, you're kind of acting as an intermediary between the sale of the contacts and the doctor?

SHAUN SCHOOLEY: That's right.

BETH DELANEY: And then are there any particular technology challenges with setting up an interface with the doctor's offices? They have different-- or do you just bring that all to the table?

SHAUN SCHOOLEY: Yeah. It's probably an oversimplification to say we just pull the data across from their practice management systems or EHRs. Somebody had mentioned it earlier there. The catalog, the contact lens product catalog is significant. There are 80,000 plus products. There are nearly 10 million active SKUs at any given point. In our product, some of the technology challenges that we face, and I think that the industry faces, and it's just you've got multiple manufacturers that all carry that many SKUs. Those SKUs need to be understood and be carried at a detailed level to be able to bring across prescriptions carefully.

You've got a dozen different practice management systems, or electronic health records systems, that are out there. Every system works a little bit differently. Fields are used differently. Even doctors use the fields differently. So there's a lot of customization to be able to pull data across correctly. But done correctly, it brings across the right prescription and gives the doctor a comfort level that, when they're selling a product to a patient, they're selling the product they prescribed and not something that's been switched or changed or it's not going to be healthy or the right product for them.

BETH DELANEY: And from the interface, can the patient pull down a copy of their prescription?

SHAUN SCHOOLEY: LensFerry is not-- the business model on LensFerry is a purchase model. It's a commerce model, right? It's meant to sell products and allow for simple access through a mobile device, browser, email. There are products out there in the marketplace that act as electronic health records or carry that sort of thing.

BETH DELANEY: Portal.

SHAUN SCHOOLEY: Or portal kind of capabilities. But that's really not LensFerry's model.

BETH DELANEY: OK, great. Does anybody have anything to add to that before we move on to our free-for-all portion of the panel? OK. You want to start with a--

PAUL SPELLMAN: Sure, well, Dr. Steinemann, you've certainly identified invalid verification requests as a concern. And others have talked, and yourself have talked about how time consuming the process could be. Now keeping in mind that verification is required by the statute. So it's not something that the FTC can just do away with. What suggestions do you have to improve the process?

TIM STEINEMANN: So we would request an expansion of the verification window to promote fewer requests that are passively verified. So expand to two business days.

PAUL SPELLMAN: How about as far as the accuracy of the verification requests, is there anything you can think that would make it easier or more likely that the request would be accurate?

TIM STEINEMANN: As I said, the phone call, recorded messages are sometimes garbled and cut off. We can't-- they're unintelligible sometimes. There's no way to respond. So written requests only. But I'm told that you can't do it through regular email because it's not HIPAA compliant.

BETH DELANEY: Yeah, we could-- I mean, I don't want to get into the HIPAA stuff. But I think you could-- there's certain things you could do. If the patient gives permission for the prescription to go with email to them, they can do it. We can-- there's other challenges, I think, with email, whether the verification request gets caught in a spam filter and isn't received.

PAUL SPELLMAN: Also telephone communications is spelled out in the statute as one of the ways. Dr. Cockrell, do you have any thoughts on this?

DAVID COCKRELL: Two thoughts. As I said earlier, I really believe a verification provided in writing where we get a receipt notice that we did, in fact, verify that and get it back to them so I know that we've closed that loop on a two-way system. And then the second thing would be that any other way to close that communication loop, as Dr. Steinemann said, I realize telephone is approved in the statue. But a robocall was not approved in the statute.

And we get a robocall that we can't respond to, that's not communicating. That's a one-way deliverance. And literally it's routine that we can't understand who it is. So, therefore, we can't respond. Therefore, the prescription gets filled, right? That's exactly what happens. So if we have a live person on the phone that we're talking to, we can actually have that two-way conversation, we can resolve it right then.

PAUL SPELLMAN: Cindy, did you have any thoughts in response?

CINDY WILLIAMS: Well, yes, especially related to your suggestion about the eight hour window. 1-800's data that we presented to the FTC did not support expanding the eight hours to a longer period of time. Because our data says that when doctors do engage in the verification process, that they do so by calling our doctor service line within two hours of the time that the verification call was placed.

And then our records indicate that we then get back to the doctor in one hour. So that's a three-hour time period to get the entire transaction done so that when doctors engage, they have plenty of time to actually get it corrected or canceled if necessary. Also, I would say, if we can think about, and I know John Graham mentioned that earlier this morning, 1-800 being a pharmacy.

If you think about doctors and the Walgreens for a prescription, for instance. When you're in the doctor's office, your prescription is usually over there electronically at the Walgreens pharmacy before you even leave the doctor's office. So that, I think, also supports the idea that eight hours is plenty of time to be able to determine whether there's a prescription in the patient's file.

BETH DELANEY: So some commenters have said that they struggled to identify the correct patient when they get-- it can be a fax or it can be a phone call. Is there anything that any of you could suggest to-- is there a way to have a unique identifier or--?

TIM STEINEMANN: There needs to be more information, date of birth, address, phone number.

BETH DELANEY: Well, address is part of the rule. But I think patients move, or maybe they have their lenses shipped to a different address. But that is part of the rule currently, patient name and address.

DAVID COCKRELL: Date of birth might help.

TIM STEINEMANN: I said that.

DAVID COCKRELL: A date of birth would help. I have four different patients with the same name only divided by the middle initial. And two of those four with the same initial, all of whom wear contact lenses. All of whom buy their lenses elsewhere. And so we often don't know who it is. We have to pick up the phone and call to see, are you the one who just sent this prescription in?

BETH DELANEY: Right. So date of birth might be a unique identifier. I know that a lot of doctor's offices use that. Certainly have to remind me of how old I am every time I go in.

CINDY WILLIAMS: Beth, could I just mention that--

BETH DELANEY: Yes.

CINDY WILLIAMS: That would be challenging for 1-800's business model. Because when patients, or when customers, are actually ordering, we don't request their date of birth. It's not a

required field. So in many instances, we wouldn't have the date of birth to give to give as a unique identifier.

BETH DELANEY: OK. Can I ask, what percentage of the online market do you think you are, if you have that information handy?

CINDY WILLIAMS: About 60%, 65%.

BETH DELANEY: OK. So what I want to do is just move on to another area that we're interested in. So one of the underlying premises of the verification framework is that prescribers would correct erroneous requests. And they'll deny invalid ones. And some say that that may not be happening or at least not as often as it should be happening. So I just want to ask the panelists, are there ways that we can motivate or encourage prescribers to pay attention to verification requests?

TIM STEINEMANN: Again, it can't be done quickly. That's been our experience. It doesn't take two or three minutes. Give us extra time.

DAVID COCKRELL: I actually don't think prescribers do not pay attention to verification requests. We all recognize-- first of all, it's our patient. We'd like to see them back. If we don't respond to them, they're not likely to come back. Second, that once that analysis is made, as Dr. Steinemann said, it takes a little bit of time to run through that. Even if you have electronic medical records like we do, it's not an instantaneous one-minute process, and it's done.

We have to make sure we transmitted the correction, the answer correctly, either yes, it's acceptable or no, it's not acceptable. I guess we don't really respond if it's acceptable. If it's not acceptable, we have to make certain that we got that right. So it's a lengthy process to do that.

BETH DELANEY: So I guess that what I'm hearing, though, from some of the comments is that people are very worried that contact lenses are being sold through passive verification. But if a seller, I mean, certainly if somebody notified the seller that the sale was invalid, they would stop within eight hours. So the sense I'm getting from the comments is that there's not enough prescriber feedback on denying the prescriptions. It's just a sense. It's from an anecdotal sense from the--

DAVID COCKRELL: I can tell you from a factual statement, in our office we respond. And we still routinely see patients of ours back three to four years later that have been buying contact lenses every single year online. And we've said no, if we get a verification request. So somehow it's happening.

CINDY WILLIAMS: Beth, can I answer about the motivation of doctors?

BETH DELANEY: Sure.

CINDY WILLIAMS: So I thought a lot about that when you brought it up in our panel discussion. And I think that 1-800 has already worked to encourage prescribers to engage in the

process. Because we've developed a best in class phone system. And just to address some of the issues with the call, we immediately identify that 1-800 800 is the person calling. It's easy to understand. We abandoned text-to-speech for all but the parameters.

It takes just two minutes of time and can be shortened down to 1 minute and 45 seconds if the doctors are getting regular calls and they utilize the IVR aspect. We allow the prescribers and their staff to pause, to replay, or to get a callback at a later time. And we did all this without being required to do so, without a rule, without a regulation, without a law being passed. Because we thought that was best for our customers and for the doctors. So at this point we believe that the prescriber should be motivated to listen to the call because it's in the best interest of their patient.

PAUL SPELLMAN: The rule currently requires that prescribers release a copy of a patient's prescription to a designated third party. This is the actual prescription itself, not just a verification request. If the FTC were to impose a time frame for responding to such requests, because currently there's no frame like the eight-hour verification frame, how do you think that that would impact the number of verification requests? I mean, could it possibly reduce the number of verification requests? And do you think it would impact the use of passive verification?

CINDY WILLIAMS: We think, at 1-800 that a time frame would be very beneficial that it would actually reduce verifications. Our data shows that prescribers only respond to our authorized requests for a copy of the customer's prescription about 46% of the time.

BETH DELANEY: Wait 46?

CINDY WILLIAMS: 46. And that those--

BETH DELANEY: Do you have an-- I'm sorry to keep interrupting. Do you have an idea of when they respond?

CINDY WILLIAMS: Yes, I do.

BETH DELANEY: I'm sorry.

CINDY WILLIAMS: That's my next point. But those that do respond do so on an average within two calendar days. So we recommend that prescribers be required to respond within five business days, which should be sufficient for busy offices or those that are on vacation or closing for emergencies. And we also believe, Beth, that the FTC has enforcement discretion. So if there was a situation where you established five days and there was an emergency and the office was closed for some time that certainly the FTC would be able to use its enforcement discretion to take all those factors into account.

BETH DELANEY: So if you're recommending five business days, the purpose of that request is not that sale.

CINDY WILLIAMS: That's correct.

BETH DELANEY: OK.

CINDY WILLIAMS: It's to have it on file for the next order that the consumer would be coming to actually obtain.

BETH DELANEY: OK. And then if you get a copy of the prescription, you have a copy that has an expiration date on it.

CINDY WILLIAMS: Indeed.

BETH DELANEY: So then you have a record. And then that's an enforceable problem for you if you're selling. You know now that it's expired. It's not a matter of passive verification happening and you don't know. You actually have a copy of the prescription and your foreclosed from selling.

CINDY WILLIAMS: I would be remiss if I didn't say that sometimes the issue date and expiration date are not on the prescription. But certainly when they are on there, you are absolutely correct. We're vested with that knowledge. And a sale past that date would be a violation.

BETH DELANEY: So Dr. Steinemann, do you want to weigh in on--

TIM STEINEMANN: I'd like a follow up to that. Expiration date and total number of lenses allowed.

BETH DELANEY: Yeah. I don't-- that's an interesting point. I mean, I think when you look to the purpose of the rule, it's to give the patient portability. And it's for sale of lenses with a valid prescription. And I think part of the background for the rule was that some patients may wear their contact lenses faster. And when you have a risk factor, one of the major risk factors being somebody over wearing them, I think the quantity-- you know, we have to have empirical data. So when we have data that shows how many contacts people are buying, which is not ginormous amounts, and when we have data that shows that people are going back for annual exams, we don't really have the quantity data that people complain about anecdotally. We would like that data. And we're hoping in the next month, if you have it, to give it to us.

DAVID COCKRELL: But we all know, depending upon the type of modality that they're prescribed, what an annual supply is. If you make the decision to leave that number off, then that patient can fill that as many times as they want in that year for multiple years of annual supplies allowing them to go through four, five years. If there's a limit on the number of boxes or depending upon whatever the modality is, then they cannot fill it more than that.

CINDY WILLIAMS: We don't--

DAVID COCKRELL: Just like a medical prescription, if we refer to the pharmacy analysis again, there's a limit on the number of times it can be refilled. There's a limit on the number of drops to be used.

BETH DELANEY: There's been quite a bit of discussion in over, since 2003, on that issue, about the intention of the act and the rule. And we continue to look at that. But I think when you look back at what the risk factors are we have to look at all the empirical data. And when we look at sales data, and when we look at health risks, and we look at when people are going for exams and when we look at the cost of contact lenses and I don't know how much evidence there is that people are stockpiling several years of contact lenses. If that's true, we would like to see it. I mean I know anecdotally it might happen. But I mean I make a fair amount of money as a lawyer. And I never purchased a year's prescription. It was something could happen. My vision could get worse.

DAVID COCKRELL: I doubt seriously there's a single doctor in this room that doesn't have that problem I just described. And that's just this room with 70 or 80 doctors in it.

BETH DELANEY: Right. I agree, it might happen. But I guess we'd have to look at the percentage, 41 million contact lens wearers. We have to look at it from an empirical perspective not just anecdotal. But this is data that we want and we're inviting you to provide. But I did want to get back to Dr. Steinemann. Because I think the CLAO, which I know you're part of that organization, I think that they had, in their comment to the NPRM, had said two business days for this proposal would work.

TIM STEINEMANN: Yes.

BETH DELANEY: OK, great.

TIM STEINEMANN: Yes.

PAUL SPELLMAN: Jennifer, did you have any thoughts on that?

JENNIFER SUMMER: Like I stated before we've been pretty successful in getting a copy of the prescription within the same business day when we make that phone call to the doctor's office. So when I polled our vision center managers, they said, we don't believe that the FTC needs to weigh in on this unless there's other purpose. But they've been pretty successful without any type of requirement.

BETH DELANEY: OK. So just from a hypothetical perspective, I mean if each and every prescriber automatically released prescriptions to their patients, would the verification framework still be necessary? So what I want to hear about mostly I guess from retailers is does verification serve a purpose, even if someone were to have a copy? What contingencies would require verification to still be there?

CINDY WILLIAMS: Well, if a person, actually the doctor released and they have their prescription, why would verification be needed under that circumstance?

BETH DELANEY: Right. If you had a perfect world where every patient got a copy of their prescription.

CINDY WILLIAMS: Well, we think that sometimes consumers can misplace a copy of their prescription. Sometimes consumers are going to be ordering, for instance, at work, Beth. And their prescription may be at home. So I think they are definitely going to be circumstances where, even with a perfect release, that we're still going to need the verification system. But certainly it would be required less. But it's still going to be necessary.

BETH DELANEY: And Jennifer, do you want to weigh in on this?

JENNIFER SUMMER: Yeah, absolutely so. I agree with Cindy. I'm a contact lens wearer. And I'm not sure I could tell you where my prescription is right now. My doctor did give it to me though. But I can tell you that we operate pharmacies. And the analogy we like to give is that, if I go to fill my prescription, my initial prescription at a Walmart and decide maybe I want to go fill it out another competing chain, the pharmacist had the discretion to do a pharmacist to pharmacist transfer.

And so the patient is no longer involved in that process. Right? The patient can say, well, Walmart Pharmacy I need you to transfer it somewhere else. And then the pharmacist per their state requirements can have that transaction occur without the patient involved. And so that is something that, I don't know if the state boards of opticianry would need to weigh in or if the FTC could help us with that.

But that might be helpful is to allow seller to seller, optician to optician to have that connection without having to either go back to the prescriber. If one optician or one seller has a copy of the valid prescription, could they transfer it using the same thought process as what's currently allowed under state pharmacy laws?

BETH DELANEY: And the other thing I wanted to ask you Jennifer was, we had talked previously about possible fraud or forgery with prescriptions. Is that an issue that you think verification would still would help a retailer if you have concerns or no?

JENNIFER SUMMER: I can tell you if a consumer is desperate enough to forge or falsify a contact lens prescription, they're going to figure out how to do it, even though maybe Walmart or 1-800 contacts catches it or a prescriber denies it the first time. They're going to be pretty creative on how to get that done. And so I'm not sure that there's a control that can be put into place to mitigate any type of wrongdoing or bad actors.

BETH DELANEY: OK. So I guess what I'd like to just ask, though, as we wrap up the panel, I don't think we have any questions from the audience. I haven't got-- well, Rich, bring them on up. We also, just to ask, in terms of best practices, should the FTC get involved in that? Should we issues some best practices? Put out a comment process and get folks to kind of weigh in on that, would that be helpful?

DAVID COCKRELL: I'd like to comment on that. I'd like to leave a comment from a perspective from a state board member from 20 years In 20 years experience on the state board in Oklahoma, we've never had those issues arise. So I don't know. And I did queries. I told you I would, our National Association of Regulatory Boards to see how big of an issue this particular thing was. It's not, so no I don't think the FTC needs to get involved in that. I don't see a problem that you would need to come in to resolve.

PAUL SPELLMAN: I know that back in 2004 the AOA had actually recommended that the FTC create like a standard verification form. Do you have any thoughts on whether that might be helpful?

DAVID COCKRELL: I think a standard form would be excellent. Because we don't get standard forms, which makes it more time consuming to sort out.

TIM STEINEMANN: I agree.

PAUL SPELLMAN: How about you?

CINDY WILLIAMS: I think when it comes to best practices, we might have agreement with the AOA that I don't know exactly how they'd be enforced. Would they become de facto rule? So in the abstract it'd be difficult to comment on that. And I may lean against it. But I'd be happy to take suggestions that you might have if you opened up the comment period. But I think what's really important to consider is that businesses need the flexibility to comply with the FCLCA in the way that makes sense for their customers and their business model.

BETH DELANEY: So we'll finish up. We'll do the speed round. Everyone can say the one takeaway you want us to take away from the panel. We'll start with Cindy.

CINDY WILLIAMS: I think that the verification is working fine. We've said that in our comments for the most part. It's really working. We'd like to see more prescriptions in the hands of patients so that they can use that during the ordering process. And we'd like to see that doctors more engaged in the calls where they want to cancel.

BETH DELANEY: Shaun, do you have anything to add to our--

SHAUN SCHOOLEY: Yeah, absolutely. Yeah, I would just say that, I mean, from my seat, technology has come a long way. And there's always open areas for opportunity and particularly in an area like this where there's errors that are introduced because of verbalisation of complicated parameters and data points. And yeah, I would think that taking in an open-minded attitude to what the future might hold as far as being able to digitize these things or have them come across in more forms that you're able to react to and react to in a way that you're always accurate. That could be a really positive, positive step forward.

JENNIFER SUMMER: So I would encourage the FTC, if you have the ability to allow for some sort of process where the sellers can communicate, instead of going back to the prescribers similar to what's happening in pharmacy, that that would be great for the patients. Because they

have the ability to actually transfer that prescription. And to the physicians on my left, I believe that would help with a lot of the issues that you have on limits of number of boxes or lenses that would be prescribed.

Because that information could actually transfer with the prescription very similar to when you're transferring your prescription, maybe a chronic condition prescription. You know how many refills are left on that prescription. So I think it helps with that issue as well. And make sure that the patient has adequate supply but still goes back to their eyecare provider for the necessary exams.

BETH DELANEY: All right, Dr. Steinemann?

TIM STEINEMANN: Communication is key, not only two-way communication but communication of choice for the prescriber. And if I can close with a statement crafted by Dr. Jacobs, past president CLAO that the renewal of these prescriptions, and particularly expired prescriptions, which may be in the seller's interest and the consumer's immediate interest, but not in the interest of the consumers long-term eye health or in the public health. This is our major concern.

DAVID COCKRELL: I do have a comment. I would like to see the FTC not move forward with the proposed rule as you've laid it out right now. And the reason for that is, as we looked at the number of complaints the FTC received over the five-year period of time that we requested information from you, and if there really are 40 million contact lens patients a year and if they really do replace their prescriptions every 12 to 14 months, over the five-year period of time, that's any place between 160 million and 200 prescriptions. And on record, that would come out to the number of complaints you received as point 0.000006%.

My point in saying that is, if it was a real problem for patients, you would have an enormous number of complaints. It wouldn't be six zeros to the left of the period mark. And so as I look at that, I've really tried to decide, is this really a big issue for patients? Or is it an issue that retailers want to turn into an issue? I think in this case, it's not a big issue. Or you'd have a lot more complaints and just don't see them.

BETH DELANEY: Yeah. As Paul just said, we're going to tackle that on the next panel. And you're on that panel.

DAVID COCKRELL: Great.

BETH DELANEY: I mean from the FTCs perspective, we feel that the complaints we do get are a tip of the iceberg. And if you don't know that you have a right to your prescription, you certainly don't know that you're supposed to complain to the FTC. So on that happy note, let's give a round of applause for our panelists. Thank you very much.

[SIDE CONVERSATIONS]

DANIEL GILMAN: We are going to have another break. But we don't have one slated right now. And I think that as the afternoon wears on, everyone there will probably be unanimity across prescribers, sellers, regulators that prompt release from the room is welcome. So I've been asked, this is really not part of our law enforcement mission, but this is as a courtesy. I've been asked to read, if you have an outstanding debt to the cafeteria, please pay your balance. He will be there until 4:15 P.M., which is to say the end of panel five, which is to say the end of this panel that's taking place right now. On to things we're supposed to know more about or find out more about.

My name is Dan Gilman. I work in the FTCs office of Policy Planning. I'm going to be co-moderating this panel with my colleague, Beth Delaney from our Bureau of Consumer Protection. Some of you may remember Beth from 60 seconds ago if you have any working short-term memory whatsoever. We are going to give, I think, increasingly short shrifts to the many qualifications and accomplishments of our participants today.

So the panelists, now I'm just going to introduce people by their names and affiliations. We do have bios, as I think you know, available that say more about who our participants are and what they've done. And I commend those to you. A couple of bits of housekeeping just to revisit something that we've been going on about. If you have a question, there will be people who collect question cards, filter some of them up here.

Steph will read every single question that's written out. Steph will not read them necessarily out loud here during the panel. We have a lot of ground to cover, but Steph will read them. If you have questions, I urge you to do that. And of course, the comment period remains open. So if you have more considered thoughts about the proceedings today or anything that we've published, please consider the public comment period.

A little thing for our panelists. I hope that we're not going to have formal presentations kicking off, except for one from Beth. We're not going to have formal presentations kicking off this discussion. If the panelists could, when you have something you'd like to say, just turn your comment card this way. And then I might see it. Beth, more perceptively than myself might see it. And we'll at least keep track and try to call on everybody.

So and then I said, well, I suppose I should say, anything I say here today, any question I might ask is my own. It does not necessarily reflect the views or curiosity of the Federal Trade Commission, any of its individual commissioners, or the Office of Policy Planning here at the FTC. I'm going to turn this over to Beth who has a few framing, very brief framing remarks about the flip side of the verification request, which is--

BETH DELANEY: Oh, we need to introduce the panel?

DAN GILMAN: Yeah, I'm going to introduce it, which is Prescription Release and Consumer Choice, after Beth, the panelists will be Dr. Edward Chaum, Plough Foundation professor at the University of Tennessee Health Science Center. Dr. David Cockrell who's past president of the AOA and a diplomat of the American Board of Optometry. Dr. Zachary McCarty, chair of the Quality Improvement and Registry Committee of the AOA. Joseph Neville. Joe is executive

director of the National Association of Optometrists and Optician's and Linda Sherry who is the Director of National Priorities at the Organization of Consumer Action. So let me turn it over to Beth. And then we'll get the discussion started.

BETH DELANEY: Right. So I'm just going to get a little bit of an overview. As you all know, prescribers must give a copy of the contact lens prescription to the patient when the contact lens fitting is complete. We call this automatic prescription release. You don't have to ask for it, it's supposed to be just turned over to you. The patient getting a copy of the prescription is one of the key underpinnings of the rule. It's the mechanism that's going to make comparison shopping possible.

So in our rule-making review, the commission examined the available evidence about prescription release. And it determined that it would be beneficial to increase compliance with automatic prescription release. To do so, the commission has proposed requiring prescribers to obtain a signed acknowledgment from their patients at the time the prescription is provided to the patient. So the commission believes that this proposal would serve several important objectives.

It's going to remind prescribers to release the prescription. It will inform patients of their rights. It will reduce misunderstandings. And probably most importantly, it'll improve the commission's ability to make sure that the prescriptions have been released. It's going to provide a record keeping mechanism. The proposed form reads, my eyecare professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting. I understand I am free to purchase contact lenses from the seller of my choice.

So on this panel, some of the topics we plan on covering are prescription release, the signed acknowledgment proposal, the pros and cons of the proposal, and possible alternatives to the signed acknowledgment form that could help ensure that prescriptions are automatically released to patients.

DAN GILMAN: OK, great. So this is a statutory requirement. We're supposed to implement the statutory requirement. And maybe just go down the row, but let's start with Linda. Your from the consumer organization, can you talk a little bit about the importance to consumers of receiving a copy of the contact lens prescription and what you've found there.

LINDA SHERRY: Mm-hm. Sure. Well, I do agree with Beth that the contact lens rule is the underpinning, I mean, excuse me, getting the copy of your prescription is the underpinning of the contact lens rule, which, of course, requires optometrists to provide their patients with a copy of the prescription without having to ask. And that's a very important part of it. But our polling, we did a poll in January of 2017, showed that about a third of contact lens wearers weren't getting their prescriptions. And many didn't even know, even a much higher percentage, didn't even know they had a right to get it automatically.

Having that prescription means that they have the option to use it to purchase their contact lenses from their retailer of choice. I mean, there's still, most consumers, seem to still be buying from the prescriber. And that could be that they're not getting the copy. I don't know. But they do trust these providers and these prescribers. And if they want to remain there, that's still their choice.

But if they want to go to one of the new places that are available to buy and save some money, because we do believe that consumers usually save money by shopping around for contact lenses.

We also believe that this helps consumers wear fresh, clean lenses and not try to over-wear their prescription.

DAN GILMAN: Maybe I could just go to Dr. Cockrell. I mean, you are a very established member of the profession, a past president of the association, and I guess you've suggested that it's routine practice in your office to release the prescription. I don't know if that's typical or not, but maybe just in terms of your experience of best practices, how do you implement this requirement? What are the procedures that you have in your practice in place to see that this is done, that this works smoothly, efficiently both in terms of the initial release and then maybe follow-up requests? What do you do to make this work?

DAVID COCKRELL: At the conclusion of the contact lens fitting in our office, across the board from all of our docs, at the time the fitting is completed, we have electronic medical records, so we literally press a button in our system to print that prescription. And that button's pressed in front of the patient. And literally we say, they're going to bring that in for me to sign. Because we don't have a printer in every examination room.

So but we tell them, we're done. We're printing a copy of your contact lens prescription. You'll have that, and we'll sign, and away they go. Now, what do we do to make sure that we did it, because every single day we have a patient call asking for a copy of their contact lens prescription. And it's always someone we've given it before. And it's probably as Miss Summer said, they've misplaced it or they've lost it or they've given it to someone and didn't get it back. It's all for the right reasons.

But we look to see, A, is it current when they call to ask about the prescription, is it still a current prescription? And when did we do it? And did we give it to them already? I want to know how many times I've given it. Because as I mentioned a few minutes ago, in one day, I had three requests and three different online retailers asking for a copy of the prescription as the third party agent. So we went we want to track those numbers. So we keep track of it inside of our EMR by the patient.

DAN GILMAN: Now, do you have any, I mean, obviously your best experience is with your own practice. But you have any sense of other practices and other models where they might have more difficulty? Of course, not every practice has an EMR. Not every practice has an EMR has the same one. What's the utility of the EMR integration or of electronic prescribing, what's missing in practices where compliance is more of a burden?

DAVID COCKRELL: We created a space inside of our EMR. Our EMR doesn't come with a tab to record it. So inside of where we have the contact lens prescription in the note box. We record who gave it by name and initials who handed it to the patient. So that's our record. We can go back and look it up. But to my knowledge, there are no EMRs where we have the opportunity to click a button and know that we record and audited.

For the friends of mine that I had that are not EMR, in those particular cases, almost 100% of them have a copy of the prescription when they write it. It's a duplicate prescription that's kept in the chart. So, again, there's no audit trail other than you have to go look up the chart to see when did they get the prescription, did we give it to them? But that's the way we did it prior. And we've had EMRs for a long, long time But that's how we did it prior to that.

DAN GILMAN: Do you know in AOA, obviously, via CMS there was a big incentive program for health care providers, physicians, hospitals, other provider entities to adopt EMR. It's not 100%, very widespread. Do you know within AOA, either for the population of optometrists versus the population of ophthalmologists and other prescribers what the adoption rate is for EMRs?

DAVID COCKRELL: I'll let Zach answer that, because he's the one--

ZACHARY MCCARTY: Certainly I can speak to that and be happy to say, I've looked at the CMS data. And the best that we can ascertain from that data is who is meaningfully using their EHRs. And for optometrists, it looks to me about 1/4 of the optometrists have any EHR and have attested to the meaningful use program. So it is not widely adopted across the United States. And there's many reasons for that.

The CMS has tried to put in place a program to, as you said, push the adoption of EHRs. Unfortunately, when they put this program into place, they made some errors. And they basically looked extensively at primary care and avoided looking at the specialties and the specifics that are nuanced with other medical specialties, particularly in eyecare. And because we have those issues, there's a lot of doctors out there that have just walked away.

They said, we cannot continue using these EHRs because they are inefficient. They do not meet our needs for eyecare and what we do on a day in and day out basis. As a local personal example, we try to work with the standards that ONC, the Office of the National Coordinator, has put forth for electronically communicating just patient data. And this panel is talking about electronic exchange of information.

We tried to talk to some of our other referring doctors. Our practice is referral only. We take care of our colleagues patients that have medical problems. I don't dispense. We do not sell. We treat the problems that are caused by contact lenses. As so we're trying to exchange this medical information between our colleagues. With one of our other providers in our community, we spent over a year and a half working between our EHR vendor and the EHR vendor of our colleague and still cannot get the systems to talk across a defined standard by the ONC.

It is a very, very sorry state of interoperability in health care today. CMS recognizes this. We are nowhere near what we need to be in order to be able to communicate electronically.

DAN GILMAN: Can I just ask a related question? Dr. McCarty I know that, as you said, you get a lot of referrals for medical care for eye problems. And we've seen that adoption for electronic prescribing of medicines has been much more widespread. Do you know, just without getting into complications, what would be adapted? Maybe later in the conversation we can get there.

But do you have some sense of what the adoption rate is? I mean, I gather for pharmacies it's nearly 100% for electronic prescribing systems. For optometrists and/or ophthalmologist separately, collectively, do you know how many are using electronic prescribing for medicines, not necessarily for contact lenses.

ZACHARY MCCARTY: Absolutely. I'd love to speak about that. So as far as to prescribe out medications electronically, the CMS data shows that's happening quite frequently for those that use EHR systems. But a big difference. If we're talking about a pharmacy, and that is what some of the retailers are trying to compare themselves to, to pharmacies, we have adequate two-way communication. If I send a prescription to a pharmacy, or they send one to me and they say, this patient wants a refill and is expired. When I click and say, decline. I get a notice back from the pharmacy saying, this prescription will not be filled.

There's a comments box. It's very legible. And we're able to put in a comment. There's oftentimes, again, we're dealing with patients if we're talking medications, they may need one month's supply. And we can put in the notes, one month supply and needs to be seen again. So we can determine, is their medical problem changed before we prescribe more medication. They make that in-person visit to ensure that eye health has not changed. And there's that great two-way communication with the verification with pharmacies.

BETH DELANEY: OK let's turn to the actual proposal itself. And I want to start with Joe. Maybe you could give us a little bit of background on who you represent and what your members feel about the signed acknowledgment form.

JOSEPH NEVILLE: Sure the NAOO is composed of the majority, the vast majority, of the large optical firms in the United States. Many are also in Canada. And collectively, the members have over 9,000 locations throughout the United States. So we have a lot of retail locations. And because of that, we also have quite a few business relationships, typically landlord tenant, with the prescribers. And so we have a nice mix of both sides of this conversation, if you will.

Not wanting to sound like an ungrateful guest, my members response to the idea was, oh no, not another form, not another signature that the consumer is going to have to put on some kind of a piece of paper. And how and where are we going to keep it? The sense was that patients and really doctors have got a lot of paperwork to deal with. And this is some more paperwork. And the way the rule was proposed was that it would be a separate form. So we are adding a piece of paper.

And so our natural thoughts went to, maybe the better approach is to inform patients of their rights. Lets make sure there's more information about their rights. So that if there is a problem with the release, the patients are more engaged.

BETH DELANEY: OK. Well, we'll shift to proposals.

JOSEPH NEVILLE: Yes.

BETH DELANEY: Before we do that, let me ask Dr. Cockrell about your, as an independent optometrist with your own practice, if you could give us a little feedback on the signed acknowledgement proposal.

DAVID COCKRELL: I think it creates a very significant burden. I looked at the numbers before I came. In 2017 we prescribed for over 6,800 individual contact lens patients. And when I think about the process of asking 6,800 people to sign a piece of paper, and in then the length of time it will take to explain to those patients, here's why you're having to sign it, because it's a ruling from the FTC that you have to do this. And then in my mind, it creates that little bit of patient doubt, which interferes with doctor patient relationship.

Then at that point in time, because our EMR doesn't have a place where a patient can sign. So we will have to literally have them sign a piece of paper and then take the time to scan that document in. It's unfortunately more than a minute. It really is. That conversation is two to three minutes for the staff and then absolutely I'm going to, I guarantee you, somebody will say, well the patient wants to talk to you about this form before they sign it. Because we have that occur right now.

So I just look at the economic dollar cost in terms of spending time explaining it. And then the one or two minutes scanning it into the appropriate spot in the electronic medicals. Because I darn sure don't want to keep 6,000 pieces of paper, 18,000 over a course of three years, and have to keep up with them.

BETH DELANEY: Could you elaborate on the creation of the patient doubt. Because that was in a lot of the comments, a sense of distrust. And we're wondering what does that mean?

DAVID COCKRELL: Well, just imagine, you're an attorney. And you've been my patient for the last 25 years wearing contact lenses. And whether you purchase it from me or not, I've given you a prescription. And next year, you come in, and I say, by the way Beth, you'll need to sign this piece of paper today acknowledging that I gave you that. Would that not give you pause to wonder, now why is he doing that? He's never done it before.

And you have a legal mind and legal training. Think about those folks who don't have. They're all going to wonder, what just happened to that doc? Why is he having to do that? Who made him do it? Now, I'm going to blame it, quite frankly, FTC. The FTC is making me do this. Well, why are they making you do that? Oh, I don't know. Or they think there's a problem that we really can't confirm. That's literally going to be the conversation across the United States.

And maybe I shouldn't speak for all my colleagues. But that will be the conversation certainly coming out of our office. Because that's reality. But that still creates a little bit of doubt. Isn't it going to make you wonder just a little bit? He didn't have to do that before. I didn't have to sign up before. And now I have to sign it. Gosh, we get questioned on every single piece of paper we have to sign, whether it's the HIPAA forms, the office policy forms. You'd just be surprised.

BETH DELANEY: Yeah. Well, let me ask Linda about this. Because this is a consumer issue. So with HIPAA, you do kind of a confusing form, and you don't really understand that your

medical records go to a pharmacy in order to get a prescription filled. So Linda, what do you think would, you know, you've heard the language of the form. And what do you think the consumer takeaway would be with having to sign another form? Would that raise a lot of questions? Would they--

LINDA SHERRY: Well, offhand, I don't think it would. I think that unless for some reason the doctors decide to try to shoehorn something in there like you have to go to arbitration to settle all your disputes or something like that. If it' simple statement, and it's there for their protection, I think that a reasonable consumer could understand that. Unlike other medical professionals in industries, optometrists are allowed to sell these very products that they prescribe. And many are also retailers of the contact lenses. So this is a conflict.

And maybe consumers don't realize it. But it is protecting them from that if they know that they have the right given to them by the contact lens rule to go and shop around. I feel that our polling has showed that, despite this right to get this copy of this prescription, sadly, many consumers are finding it difficult to get a copy. So if there was a better record of this, I believe, why would this not be a win-win for both sides.

Even if it took a minute more or two minutes more, it would establish trust. And it would establish the fact that the eye doctor could prove it was given and that the consumer could acknowledge receipt of it. So it seems to kind of solve two problems at once, at least to us. You mentioned a carbon copy that you had years ago. Well, couldn't this just be a carbon copy with the sign off? Could you, I know HIPAA was raised with email, but could you email or text it?

You said you're using electronic medical record.

BETH DELANEY: I think, yeah, we're going to definitely have a whole segment on proposals. But I see Dr.--

LINDA SHERRY: Could these things be made more consumer friendly, these receipts? But--

BETH DELANEY: If you want to fax it, definitely.

LINDA SHERRY: The the fact the consumer has the receipt is very important.

BETH DELANEY: So Dr. Chaum, you want to--

EDWARD CHAUM: Yeah, I think what you're seeing here is actually really important. This is in front of you is the evolution and the growth of medicine as we move from the paper era to electronic health record era and this transformation is not going to be easy. It's going to be long it's going to be painful but it has been initiated the HITECH Act mandates that all of us who submit electronic billing using electronic records are mandated, by law, to implement meaningful use applications in the care of our patients.

And I think this is really an incredible opportunity for us to see where we can take that mandate and apply it and use it to address some very painful issues in the course in managing our

practices. The reality is, and most people don't realize this, the reality is that the patient owns his or her health information. The medical record, the prescription in my record, belongs to the patient. I'm the steward of that information. I'm responsible for managing it. But it belongs to the patient.

And there are now applications that are being developed that have been implemented across many platforms that allow the patient to utilize a portal to go in and acquire his or her information on their own. Those portals are associated with electronic audits. They can be associated with the, not only the transfer of an electronic record that gives the patient a prescription. If it's out of date, then it's out of date, and they can't use it for a vendor.

But it can be associated with the transfer of other information, health information, educational information, reminders to come and get an examination if that's what the doctor wants. That electronic format and the interaction of that patient with his or her own information is where this discussion needs to go.

BETH DELANEY: OK. I'm going to--

LINDA SHERRY: Can I just-- OK, you go.

DAN GILMAN: I actually just wanted to ask a follow-up question of Dr. Cockrell. I think you raised an important point. A lot of practitioners are under burden of accretion of regulatory requirements. And so, even if it's a simple form, it's another one. There's a process. There's an amount of time. And I don't think we want to make light of that. I think we want to get a handle on what the burden is, whether we go forward with this proposal, a modified proposal, a different one.

I do want to push a little bit on this sort of one, two, three minutes. Because we have some substantial experience with forms. And, for instance, with the HIPAA form. I mean HIPAA was enacted some time ago. The first and then second privacy rule under HIPAA were promulgated. And people routinely signed various forms and medical practices. And I don't know whether the literature on the time spent is encouraging or discouraging. Maybe it depends on the way you look at it.

But, I mean, it seems like a lot of people don't read the forms at all. They sign the forms. They're used to forms. And we've all sat, and even practitioners have sat in physician's offices. I don't see that many lengthy conversations. I don't recall a lot of articles about, or even ad hoc complaints about, oh, this HIPAA requirement, have you been sharing my personal health information with every Tom, Dick and Harry who ask you for it? And I can't see you anymore.

I mean, you might have a one-minute conversation, a two-minute conversation, a two-hour conversation with a patient. But are you really expecting conversations of multiple minutes with each patient? You named the number of patients you see. With no other forms have I seen any literature suggesting that this happens.

DAVID COCKRELL: When-- you evidently weren't sitting in the offices when the HIPAA forms first came into compliance and we had to start using them or maybe not in rural Oklahoma. Because the reality is, every form that comes along that we've got to sign and do, it is a discussion. And I didn't say it's a 10-minute discussion. It's a one-minute discussion maybe for the front desk to say, here's why you've got to sign this as we give them their prescription. Then if it winds up with me, it's going to be another minute or two, because I'm leaving the exam room. Now I'm out of it.

So not only is it the regulatory burden that I believe is truly unnecessary, there's an economic cost. As you know, the AOA submitted our survey to you from [INAUDIBLE].

DAN GILMAN: We saw it, yeah.

DAVID COCKRELL: We can agree or disagree on the dollars. But the reality is there is a cost to paying the staff to do those things. When they're not doing some other job, they're doing that job. So there is a real cost. And is it really necessary? I don't actually have, Dr. Chaum, any patients that don't know that the records are their medical records, that they can't request their medical records any time they want.

We get those requests on a routine basis, if not daily. So I think we have an educated population that knows the records are theirs. Certainly when we give them the prescription now, they call back to ask for another copy, they know it's theirs. So I just look at this as one more job that we don't need to do that I'm going to pay someone to do that provides no real benefit to the patient.

BETH DELANEY: And so do you think that it will reduce the verifications?

DAVID COCKRELL: I think absolutely. If every single patient had the prescription in their hand every single time they had it, it will reduce them. The reality is, I can tell you from our experience, we get calls every day for another copy of prescription. So I don't know if they lose them, if they turn them in. I don't know what happens. Those folks, we get verification. We've got, obviously, a large contact lens practice, so we get verification calls, or robocalls, or faxes every day in our office. And I know how many of those we give out. So it's not going to eliminate it. It's really not.

BETH DELANEY: Well, I think--

DAN GILMAN: I'm going to go back, I'm sorry, Dr. McCarty had his tent card.

ZACHARY MCCARTY: I'm going to go back to what you just said about most patients aren't reading these anyway. What good is something as an enforcement tool if they're not even reading it in the first place?

BETH DELANEY: Well, they'd get the copy of it.

LINDA SHERRY: They're getting the copy.

DAN GILMAN: It documents-- well--

ZACHARY MCCARTY: They're not reading it in the first place. So--

LINDA SHERRY: Now, I think you should think of ways, in your associations, which are very vital apparently, how to create something that is going to give the consumer the choice to pull down their own prescription anytime they want so they don't even have to go through you. They'll be able to print it out. And if--

ZACHARY MCCARTY: I'd love to respond to that.

LINDA SHERRY: And if it's expired, you could also give them some health information. We do this for your protection. You need to get another eye exam. You can come to me, or you can go to somebody else. It's a wonderful, teachable moment.

DAN GILMAN: It might be. I'd like to give Dr. Cockrell a chance to answer. But there's a question from the audience simply asked, if a signed acknowledgment did, in fact, cause consumers to ask about the new requirement, isn't it likely that that's a growing pain that would go away, diminish over time?

DAVID COCKRELL: , Possibly, yeah. Because they're going to get them year after year. So at some point they would stop asking, absolutely. But there's also a flat line of about 40 million contact lens patients, which means over the last several years, which means we've gotten new patients every single year coming in as patients stop wearing them. Otherwise that number would have grown exponentially. So there is always going to be a constant education process.

And just to briefly address your question, as Dr. McCarty talked about the portals. We have a portal right now where we give every single patient a piece of paper. And our staff takes the time to go over to say, please use our portal. Why do we do that? Because we're incentivized by the CMS, if we get enough people to do it, we're going to get a bonus. Do you know what our percentage is?

BETH DELANEY: Slow, I'm sure.

DAVID COCKRELL: It's less than 1%, less than 1. So the fact that we can have all the portals we want, they're not going to look at them.

BETH DELANEY: Well, we'll talk about--

DAVID COCKRELL: Maybe in 10 years, they will. I don't know.

BETH DELANEY: We'll talk about portals in a second. But I do want, before we move over to alternatives to signed acknowledgment and start fleshing that out, and we're going to have Joe do that. I did want to ask Dr. Cockrell about, in the comments, we did have a lot of prescribers that are concerned about patients having to come back in to the office if they finalize a contact lens fitting over the phone. So is that something that so maybe your patient that's been coming for a

few years, and you decided to switch to a new brand with your prescriber. So you say to me, wear them for a week and see if you like them. I call you in a week and you say, OK, sure, go ahead. So does that happen in your practice?

DAVID COCKRELL: Never.

BETH DELANEY: Never, OK.

DAVID COCKRELL: And the reason for it, the reason--I really want to take an opportunity to address that. The reason it will never happen in my practice is, the end of the day, if I say take this lens and wear it, you decide if it fits you or not. It feels pretty good and something goes south, who loses the lawsuit? I can tell you right now, if that actually was brought to the State Board, and someone was sued, I'd blame the doc who did it. They didn't provide good care.

They need to get the patient back in, look at the lens, and make sure it actually fits on their eye. Because despite what we heard this morning, every single contact lens is different. I don't care if it's Johnson & Johnson's brand line, every one of those is or CooperVision's or Bausch & Lomb's, they're all different. There is no such thing as generic. Because all those parameters that Dr. Eydelman talked about, every one of them constitutes-- and I'm tell you after doing this for 36 years--

BETH DELANEY: OK, so--

DAVID COCKRELL: It doesn't work.

BETH DELANEY: So as past, president of the AOA, what percentage of prescribers do you think have that followup, that second visit is in person? Because this is a concern people have. They feel that the patient would have to come in and sign the acknowledgment form. I mean, we'll think about a work around. I mean we could have an email signed acknowledgment where you save the email receipt. And that's good enough if they don't come back in. But is this going to be a real issue? Or--

DAVID COCKRELL: I would really be surprised if it's less than 80% to 90%. And it should be 100%. I can't imagine anybody, accepting the liability of telling a patient to go wear something and not looking at it after the fact. We can certainly get the numbers from our contact lens section. But I can't imagine it. But the onus is on us to say, that thing fits.

BETH DELANEY: So are we ready to move to-- did you have a followup, Dan?

DAN GILMAN: Well, I wanted to ask about, I mean, Beth is going to ask, and I think it's important to ask about alternatives, possible alternatives. But I'd like to think about alternatives with a small a first. So not something radically different, but there's a federal statute that demands prescription release upon completion of the fitting, upon the patients request, upon request from an authorized third party.

We, a law enforcement agency, are charged with implementing and enforcing this requirement. So one idea to document the actual release is this signed acknowledgment form. It's a pretty brief form. And I think the initial proposals didn't say it had to be papers, paper, electronic, you can scan what you want. But let's think about alternatives with a small a. And just put a little proposal.

We had one proposal. Now we're going to slightly modify a proposal. We're going to ask, is it better or is it worse? What's a little better way of doing this as opposed to doing something else entirely? More reliable from the practitioner's standpoint? More economical from a practitioner's standpoint but not something completely different. A more efficient way of doing this.

DAVID COCKRELL: Is that question for me?

DAN GILMAN: You, and then anybody else who wants to chime in. My technical suggestions about the cards have obviously, I'm not an engineer. This is terrible. Nobody's taking me up on this proposal. But sure, why don't we start with you. And then anybody who wants to do this thing can chime in.

DAVID COCKRELL: Well, as you know our recommendation is for appropriate signage. There are many different government agencies that require us to post signage for people. And I'll let Dr. McCarty address that, maybe it's specific. But I truly believe that appropriate signage at the front desk where the patient signs in, at the front desk where the patient exits the office, if that' signage is there and clear and legible,

I believe that's enough. I really do. I think that's appropriate. It educates them. I can't imagine that there's really a third of the people who don't realize they can get their records or their prescription, so I believe that will work. And we've also seen it in California demonstrated where the survey we did was above 90% of the people believe that it's sufficient. That's a pretty big state.

EDWARD CHAUM: Thank you, Dr. Cockrell. And I'll take and say, looking at your sister agencies, we deal with the Office of Civil Rights. They deal with some pretty hefty issues, discrimination. It's a much bigger issue than I think this little piddly thing we're talking about contact lens release. They feel that it is sufficient for section 1557 to post a sign in our medical practices saying, we do not discriminate. When such an issue can be done with a poster, why can't we do it with a poster with contact lens release?

BETH DELANEY: Linda?

LINDA SHERRY: Despite, that's a good point. Thank you. I think that signs don't really work. I think they can be hidden. In California there is such a requirement that you post a sign about your rights to get a copy of your prescription. And having learned of that, we took a look around just in San Francisco and in San Jose. And we did not see a lot of compliance. Now maybe it was sitting behind a potted plant somewhere. I don't know.

But there was not a lot of compliance. And with something like that, you do have to have the ability for law enforcement, in this case the FTC, or the state enforcement people to go out and say, hey, you're not showing that sign. And that seems like pie in the sky. I think that the money is better off put towards educating consumers as to what they can gain, say for instance, if they used your portal.

So in addition to having them sign this thing, why don't you give him a couple of minutes of education about the fact of, look, you have a cell phone. You use it every day. You have it in your pocket. You live with it. Try pulling down this app. Try using this portal. You will have access to everything you need. You will be able to tell us in the portal, hopefully, that you want to use 1800CONTACTS or that you want to use, I don't know what, Simple Lens or whatever you want to use. But you'll be able to have your preferences in here. And it will be easy.

And I understand that I have at least six of these medical record things now. So they do get confusing, and you forget the passwords. But I still think that we have to present them in a way that is beneficial to the consumer and the consumer understands that these are helpful things that will save them time and money in the future.

BETH DELANEY: I want to go to Joe. Because I know, yeah, I know you turned your card.

JOSEPH NEVILLE: Our starting point was signage. And we talked about the California example. Because our members that are out there try to comply. What the percentages are, I can't tell you. We had the AG look. And we passed the test. So we were happy. But we thought that signage, and we couch it in terms of a prominent place, so it's like Dr. Cockrell mentioned, someplace where the patient is going to be getting that prescription finalized and paying for the services and perhaps the product. Make sure there's a way.

But our other approach, and maybe this is a little a, Dan, I'm not sure, is on the theory that the FTC needs an enforcement mechanism, instead of a separate piece of paper or a separate electronic thing, incorporate the notice and the acknowledgment into documents that already exist. Perhaps that could be on the script itself at the bottom. I looked at the script for my doctor. There's a lot of room on that piece of paper. He had a little counter sign.

But allow the doctor the option to figure out, how can I demonstrate that I'm complying with this rule? Is it email transmission, fax transmission, some mechanism that exists for all the different ways that prescriptions can be transmitted.

BETH DELANEY: So what we would do is we would make something a little bit broader saying to prescribers, you need to have some sort of record keeping mechanism. And then it wouldn't be a one size fits all. We'd let the prescriber kind of figure it out. And maybe we would offer some guidance on different ways to comply with the requirement?

JOSEPH NEVILLE: That's exactly what we're thinking. But we also think you have to couple that with enforcement and make sure that the community knows that enforcement is happening.

BETH DELANEY: So before we move off of signs, did anybody else want to add anything with signs? OK, so we did-- when we got the sign as an alternative, we did reach out to the California State Board of Optometry. And there's really nothing there in terms of enforcement of the signs, or even them looking for the signs. They didn't have independent inspection authority until this year. So basically, they would only go into an optometrist or a retailer to get documents or they had some other reason to be there.

If they noticed the sign wasn't there, they wouldn't dock them for it if they put the sign up then. So there's really no evidence either way. I just talked to the executive director yesterday. There's no evidence either way that it's working or it's not working. So we didn't get a lot of comments that say it's working great in California. But we went to the source. And there is really no evidence. And there is a perception that putting a sign up isn't actually evidence of the prescription was given out. It's just evidence that a sign was posted.

JOSEPH NEVILLE: Well, to us, it's a part of the education process.

BETH DELANEY: Right is it education?

JOSEPH NEVILLE: And that to us is important as a starting place.

BETH DELANEY: It's a starting place. Great. Dr. Cockrell?

DAVID COCKRELL: Yeah, I also, after we had that earlier conversation, I called the state board in California as well and introduced myself as a state board member of Oklahoma and asked them how the process was going. And they did say what you said. But then I said, OK, what do you do-- what will you do if that's brought to your attention? Because as a state board, their job is to not look after the professional or the practicing OD, their job is to look after the public. They're there to act as that enforcement measure on the state on behalf of the patients.

And so in my mind, if you have that requirement of signage, now that's a federal government requirement that the signage has got to be up. If a patient has any complaint and it goes to the state board, the state board will act, every single one of them, will act judiciously and work in favor of the patient to enforce that process and whatever things they do.

And I don't know what enforcement process the FTC has in mind, whether that's a fine, whether that's something else. But I know that when the state board calls, every doc's worried about the jeopardy of their license.

BETH DELANEY: Right. I guess from our standpoint, I mean, if a sign is not posted, a patient wouldn't know where to complain. They wouldn't know that a sign needed to be posted. So it would involve the FTC visiting spots to make sure the sign was up. And we did do a little bit of a, let's send out some investigators in California. And they visited 15 locations, and no signs were found. And they did ask the receptionist about them. And no receptionist knew about a sign requirement. So I don't know if that was just the luck of the draw. But that was kind of a sad result from--

DAVID COCKRELL: It could be. But you may remember my comment that one of the problems I said when we first discussed this idea of signing a piece of paper was that the average job tenure in the average optometric office was 16 months. And that the average office at 3.4 staff. And that within a two to three-year period of time, all those staff have gone. And they're all small businesses. So the institutional memory is gone. The reality that that piece of paper is getting given out to be signed is not great either.

DAN GILMAN: Oh, I'm sorry. I mean, maybe that's true. But the office, that's not the turnover for offices, right?

DAVID COCKRELL: That is the turnover for offices.

DAN GILMAN: So I'm-- no, no, that the whole office disappears within 16 months?

DAVID COCKRELL: If you've go three staff--

DAN GILMAN: You go out, your practice--

DAVID COCKRELL: If you've got--

DAN GILMAN: Rises, and falls in 16 months?

DAVID COCKRELL: If you've got three staff, and they average 16 months, if they're not all hired at the same time, no, it's not 16 months.

DAN GILMAN: No, I get it . But let's say Dr. Smith and et all has an optometry office. That's not the average life of an optometry office. The office as an institution knows, I mean, boy that sounds like a nightmare having to re-educate everybody about every single--

DAVID COCKRELL: It is a nightmare.

DAN GILMAN: Wait a minute, every three months.

DAVID COCKRELL: It is.

DAN GILMAN: You persist, right? So if there's a sign on month one, and one receptionist leaves, you wouldn't expect the sign to disappear, would you? The office is responsible for that. I mean, this is not--

BETH DELANEY: Well, I--

DAN GILMAN: A random sample. This is not a big end. But I'm thinking, if we sent people to 15 offices--

BETH DELANEY: No, I think-- I think-- were you talking-- you were talking-- he's talking about signed acknowledgment.

DAN GILMAN: A signed acknowledgment, but a sign, if we didn't find a sign in 15 out of 15 offices, then that that's not because the receptionist left. That's because the office doesn't have a sign, right?

DAVID COCKRELL: Well, yeah, clearly there's not a sign there. Maybe there was and maybe there wasn't. We don't know whether there was or wasn't, whether it did get thrown away, whether it never got put out. What we do know is, if the regulation went out and they're not complying, it's a pretty simple process to send that complaint into the state board. Every single state board has a DAG. Every single one of them is required by law to respond to a written complaint. That means they're going after the doc. That simply.

BETH DELANEY: Well, so what you're--

LINDA SHERRY: If they don't know it, they're not going to--

BETH DELANEY: With your staff turnover example, I mean, I wonder if that sheds a little bit of light on why some patients aren't getting a copy of their prescription. I mean--

DAVID COCKRELL: Possibly.

BETH DELANEY: You hand over the prescription yourself. But if staff turnover is preventing prescriptions from being released the way they should be, I mean, that is the law. And that has to be fixed. So at the same time that offices are fixing that problem, the signed acknowledgment would be a piece of that. I mean, it would almost be a better reminder for staff to turn over the prescription than just-- it would be an affirmative act that might help remind them to do it.

DAVID COCKRELL: You are correct. I really wish I could describe what it's like running a small business with three to four staff working for you and the fact that everything doesn't happen every single time. But the FTC has now said, we're going to enforce. You've got to have that piece of paper signed as well. Not just that you got to give out the prescription, but you've now got to be able to produce that piece of paper three years out. I realize it sounds simple to you all. But--

BETH DELANEY: Well, no, we're--

DAVID COCKRELL: They're not.

BETH DELANEY: We're holding a workshop because of these issues.

DAVID COCKRELL: Right.

BETH DELANEY: It doesn't--

LINDA SHERRY: They're not just simple.

BETH DELANEY: We're not dismissing them. And we're not-- we really want to hear. And we want more comments in the next month. I don't want our grilling of you by Dan to make you think that we're not taking you seriously. We really, no, no, this is a great conversation.

DAVID COCKRELL: Yeah, I think he makes good points

BETH DELANEY: It's making it much more interesting than if everyone just had a canned presentation. So we are listening, though. And that's why we're all here today.

EDWARD CHAUM: I think this gets to the issue of trying to migrate this into an electronic format where there is an audit trail, where there's electronic memory, where there is meaningful use demonstrated that brings value to the practices. I think it clearly needs to move in that direction. And it seems like there are practices in which that will be a shorter term migration and practices in which that will be a longer term migration.

But ultimately, providing that information electronically, providing patients access to their information electronically so that they don't have to-- so they can do it independently with valid prescriptions that are overseen by the practice, takes away a lot of the pain that's being discussed here.

ZACHARY MCCARTY: I think that since Dr. Chaum brought that up, it's good to interject and say, I think there was a misstatement earlier that HITECH demands that the practice put in EHRs. It is not a demand. Is not a requirement of providers. Some providers will see penalties for not having an EHR. But it is not required practice medicine nor optometry or ophthalmology in this country under that law. We are in a very, very under-utilized fashion at this time.

Our practice, I'll just go ahead and use our practice for an example. Last year we saw over 26,000 patients at our practice. Of that, we have support, and we've had for four years now, so this is not new. These patients have seen it. They know, we've been advocating, go use the portal. We have made every attempt to be meaningful users. We have tested meaningful use since the inception back in 2011 with our EHR.

We've offered it to over 84% of our patients. 8% of those 26,000 choose to engage in some fashion with our patient portal. Of that, 1% actually message us through the portal. For those asking for a medical record request through the patient portal, and mind you, 26,000 patients across Nashville, Chattanooga, and Knoxville, we're not in the boonies. We're not in rural America. These are metropolitan areas. We have had approximately seven patients ask for their medical records through the portal.

We've had two that have asked for their medical prescription through the portal. And of course, we don't provide, we don't do contact lens prescribe in our office or glasses prescription. So we don't have that release within our portal. But many portals don't have that. Because again, the portals are written to the high tech standard, as Dr. Tom alluded to.

And the ONC set those standards. And they ignored eyecare. So it's not there. You can't audit the record and say, was it released? Because most these portals aren't built for that. And you're

talking about hundreds of different disparate EHRs that are not prepared for this. And if you think moving Congress or government is easy, try making an EHR vendor improve their system to help the provider.

BETH DELANEY: Linda, did you have a question?

LINDA SHERRY: Well, I mean we heard about LensFerry today. So the potential to do these kinds of things is there. I would like to know, though, as far as, I know there's a little pick up on portals. But how does the little pick up on portals compare to the verification request you're getting from the online vendors? Is it commensurate or are the people who are not signing up for the portal, say if they're 2%, are you also getting like 2% of people coming in from online vendors asking for verification? So is it commensurate at all? They'll use an online vendor but they won't use your portal type of thing? I'm just trying to understand their behavior.

DAVID COCKRELL: Yes. The simple answer to that last question is yes. They will use their online vendor to purchase lenses. And then when we go through verification where they don't use our portal.

LINDA SHERRY: So it's all the online vendors put their heads together and built a verification system, would you guys use it? I mean, would it be, could it be used by everyone? Or do you think it just would-- nobody would agree or it would be anticompetitive idea?

ZACHARY MCCARTY: I think the numbers kind of speak for themselves right now.

DAVID COCKRELL: Yeah, I would--

DAN GILMAN: So what would make it--

LINDA SHERRY: Why day they like to go online but not use the portal? This is-- I mean, do you ever survey your customers to find out why they feel this way?

BETH DELANEY: I think Dr. Chaum knows something about that, right?

EDWARD CHAUM: Well--

BETH DELANEY: A little adoption--

EDWARD CHAUM: Again, just looking at the literature about portal adoption, Dr. McCarty is correct. Adoptions have been very low across the board for most portals in various aspects of clinical medicine. Even Kaiser, which has a great integrated health care system has relatively low portal use at this point in time. I think what you're going to see is, as patients now are beginning to have experience interacting with their banks and they're making airline reservations and doing all these things on the phone that the availability of applications to interact with patient portals is going to, like with LensFerry, is going to open that up.

You're seeing that a tremendous amount of growth in the contact lens market is in the 18 to 30-year-old group. That's where the greatest growth is. And so these are millennials who are going to take advantage and drive this adoption. There are a number, there are four or five different features to portals that have been identified as having a negative impact on adoption.

The first one is health literacy. There are many people who aren't comfortable accessing information online. And for those patients, it may be a difficult challenge. It may be an insurmountable challenge to get them to interact with their portal. But as the younger population of patients grows and this becomes part of all of our daily lives, doing those types of interactions, I think, are going to become more part of the norm.

The other things that limit adoption of portals are the provider interactions as well. And I think you've good example of providers that do a good job of trying to interact with their patients and are seeing the frustration at getting those patients to adopt. But many electronic portals that where the physicians are not interacting, that clearly has an impact on whether or not the patients adopt and use the portals.

The other two features of portals that have an impact on utilization are usability. How easy is it to function? How many buttons do you have to push to get where you want to go to get the information that you want? And utility, what are the features in that portal that provide value to the patient? And so the development of new types of portals like Blue Button, which is a VA based system that's widely adopted in the VA System and in the Department of Defense.

It's a one button access for patients to access all of their information. So it's easily usable. It has high utility. It provides patients access to a variety of information. These types of applications have already been developed, have already been implemented in many electronic health record systems. And you're seeing innovation like in LensFerry new apps that are going to come along that are going to hopefully drive adoption in the future.

DAN GILMAN: Can I follow up with both Dr. Chaum and Dr. McCarty? So, I think we want to both track the promise of some developing utilities but also be aware of some difficulties including usability difficulties people may have, whether they're patients or practitioners. What, and going back to small a steps, what are things that might be done to facilitate? And this could this could be electronic recording and transmission as an option.

We heard, and indeed it need not be electronic, we heard about integration of the prescription with the acknowledgment. We've been relatively unprescriptive about the form of the prescription, maybe less than in the medical realm. But there are statutory requirements for a contact lens prescription. And there are requirements in the rule.

I would say in terms of little a, what do you think is the promise of maybe, we have these two panels in a row of providing either requirements or guidance that would be a little more prescriptive about the details of the prescription as one issue about integrating the prescription itself with the acknowledgement of the prescription, about doing this on paper, electronically, either. Or what can we do to facilitate this.

And part of what I'm thinking about is between the two panels exploring ways for there to be a little more of an economic trade-off so it's not just another requirement. But maybe there's another requirement or some substantial guidance that has a pay-off. The transmission of the information, canonical information, inspectable information is easier, cheaper, and more reliable. So there's less of a bother with these calls.

Maybe not the 1-800 calls but whatever the source, the calls that your practice doesn't like, the incomplete calls, the hard to understand calls. What are some things we can do to either integrate these functions or facilitate the development of these things?

ZACHARY MCCARTY: I think that's a very, very big challenge. I mean, when you get up in the ivory tower, it sounds great. You're up there robo-signing on prescriptions and say, oh, this will be wonderful. It will be easy to implement and adopt this into technology. And the reality is vendors have to be on board. And right now the EHR vendors are overwhelmed with trying to make changes just to keep up with the change in requirements of the CMS, of the MIPS program, the formal meaningful use program, the advancing confirmation.

So much of their resources is devoted to already the regulatory notion of what's happening at the moment. And so unless you can bring the vendors on board to make those changes, even trying to change and add things to prescriptions takes vendor changes. And again, it wouldn't be just one, two, three, four, five EHRs, but there are literally hundreds of EHRs. Some are eyecare specific. Some are not eyecare specific. But they're all use by eyecare providers. Those would all have to make those changes.

And even to transmit that information, again, the standard does not exist. So unless the FTC suddenly has the ability to define those standards and put in some type of enforcement vendors to comply, I think we're looking at a fantasy world at this point. Yes, it would be nice. Yes, it would be beneficial. But are we there yet? No. And will we be there in five, 10 years? That's a crystal ball that's very tough to look into and see.

EDWARD CHAUM: I would disagree a little bit. I think Dr. McCarty is absolutely correct that there isn't going to be a lot of buy-in from the EHR vendors from a practical and market perspective. Optometry and Ophthalmology are very small markets. And they really don't care about us. They just don't. But I think within the existing structure of electronic health records, there are relatively simple work-arounds that we already use that can address some of these issues.

So, for example, there is no formal function in our EHR where I can click a button and it will populate a field with the patient's prescription. But I can take that patients prescription as an image and download it into that patient portal with a click of a button. And I can take an educational material with a click of a button and put that there. And then send that and the patient will get an email that says we have information for you in your electronic portal. Please log on. And that information is waiting for you.

And so there are, I think, simple work-arounds that will allow us to provide that information. Maybe there's still some pain associated with it. But it's electronic. It creates an audit trail. It

creates a permanent record of compliance on both ends. It allows a touch to the patient, which is, I think, has been an issue here today. We all want good, strong relationships with our patients. And it wasn't my intention to imply that that shouldn't be part of our practice. It's part of all of our practices.

So these are touch points that allow us to reengage our patient, do what we need to do, what we're mandated to do as covered entities and yet still try and bring some functionality and move this process into the future. Because the reality is, in five years, all of our patients are going to have all their health information on their phones or some chip. I mean, we all know this. And so the question is, how do we help to migrate it more effectively maybe with little a steps to start.

Get patients engaged in our practice. Send them an email. You have a-- I have a dentist appointment next week. I got an email from my dentist saying, you have an appointment. Please contact us. I got a text message saying please confirm. So little baby steps that get patients engaged in interacting with you in your practice as we move forward in this new era of electronic records. I think we'll ultimately gain traction and make it easier for patients and for ourselves.

ZACHARY MCCARTY: I wish audit logs, and I should have brought one with me to show you what these EHRs produce. But when you speak about audit logs, Dr. Chaum or Dan if you ever looked at one--

EDWARD CHAUM: Bu you know--

ZACHARY MCCARTY: The voluminous data that comes out of those in trying to track back and the amount of staff time reading through those to say, OK, where does it say in here that I printed my prescription? Yes, audit logs exist in EHRs. Is it intelligible or an easy to find format? Most definitely not.

BETH DELANEY: Well, let's--

ZACHARY MCCARTY: The ones that we've looked to.

BETH DELANEY: Let's take it back a step in like the way Joe had framed it, in terms of, it's not a one size fits all. So maybe some people could start moving towards audit logs and portals. But what are some of the other-- I want to talk about some of the other alternatives to singed acknowledgment as well. So let's just explore a little bit more the carbon copy duplicate angle. Is that doable?

I mean that's not a signed acknowledgment. There's not going to be a disclosure. So it doesn't have the consumer ed angle. But if you had two copies of the prescription, and you had the patient sign one of them, and you put that back in the patient folder, would that work? Would that-- is that one of the options that we could do?

DAVID COCKRELL: Is that for me or?

BETH DELANEY: You or Dr. Joe or Dr. Cockrell.

DAVID COCKRELL: Joe, you want to go first?

JOSEPH MELVILLE: Well, that's an idea that we have. and in consulting with a few of our members, they didn't reject that idea. They thought that with the kind of prescription forms that they know that their doctors use, that's something that could be incorporated into the script. There are a few states that have prescribed what the prescription form must look like. So forget New Jersey, for example. And I think there's one or two others.

But the sense was, that would be an easy way to do it. And it quite honestly would be may be your one sentence. I acknowledge receipt of my prescription. And then I sign it. So it's kind of both. Whether that's practical or not from the practitioner's point of view, that's the question that we're exploring.

DAVID COCKRELL: I'm trying to think how that actually accomplishes your goal if you put that on the actual contact lens prescription itself. I mean, the doc's already signed it, right? They're signing it to give it to them. If that's part of the prescription, so be it. But in my particular case, remember, well, I guess I'm pressing the button, then I'm signing it later anyway on electronic medical records. So I'm not going have a duplicate of it. But I've already got my audit trail if it's producible, if it needs to be produced.

You know, I don't see that in and of itself is a problem. I'm going to go back to what Dr. McCarty said. There's only 25% of the ODs that are actually using electronic medical records at this point in time. So it's going to have to be some format obviously other than electronic audit trail that you use. I don't agree with Miss Sherry that 30% of the population has no idea they have a right to their record, to their contact lens prescription, I think, is what you said, or a third is what you said. And that could well--

LINDA SHERRY: Through a poll.

DAVID COCKRELL: Right. And--

LINDA SHERRY: Yeah.

DAVID COCKRELL: Right. I could-- unfortunately, I could do the same one and get 90% that do depending on the population I use.

LINDA SHERRY: Well, ours was commensurate with the FTC findings as well.

DAVID COCKRELL: I understand.

LINDA SHERRY: And they were done separately.

DAVID COCKRELL: I understand. But my point is that-- well, I've made my point. I don't need to reiterate it.

LINDA SHERRY: You know, I hear from all of you the frustration. I really hear the frustration. It must be quite frustrating to deal with, number one, these terrible patients that stockpile boxes of lenses and lie about having been your patient. Oh my word, they just sound awful. But I think that if everyone puts their head together and works together to solve this particular problem, that will allow more competition in the marketplace, more people to use the online vendors if they want.

It's a 12-- maybe it's a $12 differential in the price or something of a box? But that means a lot to a lot of families. And the fact that you have some flexibility on price yourselves shows me that this is something that can help all consumers in the end if we get it right. I don't see why the two sides are so completely far apart at this point.

ZACHARY MCCARTY: You know, I think it just goes back to what is the heart of the matter? Are we looking for a solution for a problem that doesn't exist? Dr. Cockrell already expressly said with the owned data that we had to request through the Freedom of Information Act, there are less than 0.0003% of complaints?

LINDA SHERRY: OK, well we would disagree that--

ZACHARY MCCARTY: 41 million.

BETH DELANEY: We would disagree that--

LINDA SHERRY: Oh, people don't complain about things.

BETH DELANEY: OK, we would disagree that complaints are an indication of prescription release. But this morning, we did have questions where people in the audience were saying that their state has a 100% prescription release rate or other things that are higher. This data has not been provided to us. So please submit that in the comment process. And we will take a look at it.

And you can actually email it to me directly. And this comment also says the national data is very different as well. It's a 100% release in our state. Doesn't say what state it is. We'd like more information about that. Dr. Cockrell? Or, Linda, I'd interrupted you, Linda. So you can finish and then Dr. Cockrell.

LINDA SHERRY: Sure. Is this our wrap up or-- because I mean I had a question.

BETH DELANEY: No it's not the wrap-up, no.

LINDA SHERRY: For the eye doctors if they use--

BETH DELANEY: No, let's--

LINDA SHERRY: Yeah, if they, in fact, use the excellent education materials that are available out there in their offices. Do you have these there on the tables and all that and explaining to folks what's going on?

DAVID COCKRELL: We put them in their hand. You know, I think one of the things, and some of the frustration you hear from the doctors in this room is, the reality of that is as Dr. Steinemann said and all of us has said is, contact lenses, as great a products as they are, are not without harm. And we wind up dealing with the harm. And when I look at a number like the paucity of complaints that were turned into the FTC, and perhaps people don't complain.

But they certainly do in my office. And I guarantee I've had more complaints in my last five years than was turned in on contact prescription released to the FTC. So I have to look at those as real numbers. If someone went to the effort to write those out, they're real. That's where Dr. McCarty says, is it a solution in search of a problem?

None of us want to keep a patient from having their contact lens prescription. None of us do. The reality is, it's federal law. If there's someone out there who's silly enough to not comply with that, that's their problem. And they're going to be held to a standard. But the reality is that I don't think that, even by signing that form and increasing another regulatory burden on another small business is going to be helpful.

BETH DELANEY: Let's move more towards-- let's talk more about alternatives. Because we still have a few that I'd like to get through.

LINDA SHERRY: Beth, could they just take a picture of it? Would that be appropriate by law to send to the-- I mean, if the patient themselves took a picture of the prescription at the office, was encouraged to do so on their phone, if they had a phone. Would that be enough to have something they could send to 1-800?

BETH DELANEY: Yes, that is enough. But you have to be given the prescription in order to do that.

LINDA SHERRY: Right. But you know--

BETH DELANEY: Let's talk about another way of, like, a lot of commenters have complained about, if I have to do this form with every patient and I have to save every single one of them. Let's talk about a hybrid solution and get your feedback. What if what if the signed acknowledgment form was came along with a patient bill of rights but you only have to do it for every new patient. Like if you've a recurring patient, you just execute this once?

Do people think that something like that would work? So the first time I visit Dr. Cockrell, his receptionist gives me the patient bill of rights and says, you know, gives me the signed acknowledgment form. I have a right to my pre-- I've been given my prescription. I get the education that I have a right to it. Would that be OK?

DAVID COCKRELL: I guess I have several comments on that one. I've never heard the term patient bill rights until we had our conference call last week. So it was a surprise to me to hear that was being considered by the FTC. Then when I went back and did some research, I realized that 1-800 actually submitted that idea. So I'm still surprised to see it discussed.

I'm also surprised to see that, for some reason, the FTC would think that the optometrist and ophthalmologists of this world need a patient bill of rights. And the dermatologist, who also supply products and the dentist who also supply products and the orthopedics who also supply products--

BETH DELANEY: OK, so let's just say consumer--

DAVID COCKRELL: I mean--

BETH DELANEY: Education about the fact that you get a copy of your prescription. We'll take away tho--

DAVID COCKRELL: I'm all for consumer education.

BETH DELANEY: OK.

DAVID COCKRELL: But not the other issue. Because, again, it implicitly--

BETH DELANEY: Sure, OK.

DAVID COCKRELL: --implies we've done something wrong.

BETH DELANEY: So we'll reframe the proposal, which is, you alert the patient that they have a right to their prescription and you have only new patients execute it. Would that be a hybrid solution? Joe, do you want to weigh in on that?

JOSEPH MELVILLE: Well, it's a solution for educating the patient. And we think that makes a lot of sense on the front end. If your goal is to have a means for the prescriber to demonstrate that they've actually handed over the prescription--

BETH DELANEY: Well, it'd be to-- right, so at least with the first instance, they would collect a signed acknowledgment.

JOSEPH MELVILLE: If it--

BETH DELANEY: And they would give patient education that would kind of help further down the road. So it would still be the signed acknowledgment. But it would be accompanied by patient education that then wouldn't require to be re-executed every year.

JOSEPH MELVILLE: Yeah, we think that that makes sense as long as it can be part of an existing form. In other words, it's not another piece of paper. So it could be-- I've seen too many intake forms that are top to bottom 10 point type, and they're full. So I'm not sure about the practical side of that. But if it could be incorporated into something that already exists and in that way the patient is seeing it and needing to sign it, we think that makes sense.

BETH DELANEY: Now should we have a safe harbor for prescribers that do not sell contact lenses? And how would we do that? Is that a way that would decrease the burden?

JOSEPH MELVILLE: For the NAOO members where most of the affiliated ODs do not sell the product, yes, it would relinquish the burden.

BETH DELANEY: They don't get--

JOSEPH MELVILLE: And we readily--

BETH DELANEY: Any sort of profit from the sale of contact lenses?

JOSEPH MELVILLE: Well, the way we look at it is that if the doctor is employed by the optical establishment, so even though they may not physically sell the contact lenses, that store they work for does, they wouldn't be part of that exemption. If there was some sort of a bonus arrangement, I don't think they should be part of the exemption either. But if there's no bonus arrangement involved in the separate optical sale of contact lenses, then we think that exception makes sense.

DAVID COCKRELL: I don't. You're either required to give a prescription or you're not.

BETH DELANEY: No, no, you're required to give the prescription. It would just be you'd be exempted from having to execute the signed acknowledgment form. Because you don't sell contact lenses, so you're--

DAVID COCKRELL: So implicitly the rest of us are thieves?

DAN GILMAN: No, no. I think it's a fair question whether it's better or worse, I think.

ZACHARY MCCARTY: Yeah, you could--

DAN GILMAN: So one response is, this is worse because it introduces uncertainty and difference in the practice. Another is, this is better because practitioners who have no interest whatsoever in lenses are-- we just want your feedback.

DAVID COCKRELL: Then I would ask this question.

DAN GILMAN: Mm-hm.

DAVID COCKRELL: How in the world could you look at every commercial contract and know whether that doc who isn't physically selling them is incentivized in any other way, whether it's a decrease in the rent space, whether it's advantage in something else? I think if you're going to apply this, you're going to have apply it across the board. I'm not intimating any illegal behavior. But there's many different ways to incentivize providers, right?

There are many different ways the contracts are written that I've seen come through our state board where a doc is incentivized for action X and had something to do with item Y over here that was not tied together on a bill.

DAN GILMAN: I don't know how complex the job is in the space. But certainly there are many different types of contractual arrangements.

DAVID COCKRELL: So I don't see how you can separate that out and exclude anyone.

LINDA SHERRY: It does sound that it would be simpler to have one law for everyone.

BETH DELANEY: So let's, I think we're right about at the end of our time, so let's do our wrap-up and have everybody kind of give us a thought for the takeaway. And we'll start with Dr. Cockrell at the end.

DAVID COCKRELL: My request would be that whatever action the FTC takes, that they would keep uppermost in their mind that patient health care is also part of your charge. It's not just commerce and not take an action that might in anyway jeopardize the patient's health care as you also take an action that is going to increase the burden on on a small business. That's my comment.

BETH DELANEY: OK. Linda?

LINDA SHERRY: Well, for us getting the sign-off on the prescription copy and keeping it for X years is not, as required anyway for medical records in many places, it's just really not a crazy burden. It would seem to be, as I said before, a win-win. One side has something to prove. And the consumer can't really come back to you and say, you didn't give me a copy of my prescription. The online prescription renewal for contacts, and for that matter glasses, saves consumers and taxpayers money.

It saves time and increases convenience, increases access for rural and medically under served communities, and it promotes eye health. So I think we do need to be able to give people the ability to easily renew their prescription online and also to get a copy of it online from some sort of portal or from the doctor's office themselves.

I've learned a lot of things today. And I appreciate the other side, the views of the side that don't want this update to be promoted the way it is at this point in time. But it does seem that it would be most protective for consumers to be able to have something to hang their hat on that they got their copy of their prescription.

BETH DELANEY: Joe?

JOSEPH MELVILLE: Well, because automatic release is the law, and enforcement should be a part of that, we think, give the doctors option to demonstrate compliance. And that's really our key takeaway.

BETH DELANEY: Great. Zach?

ZACHARY MCCARTY: I'd have to speak and say, that as you looked at the other government agencies, they've been mandated to start looking how to decrease regulation and not increase regulation such as what this proposed rule will do. Just yesterday, CMS recognized that health care providers are leaving the profession having increased burnout because of this over-regulation.

BETH DELANEY: But not optometrists--

ZACHARY MCCARTY: Of the profession--

BETH DELANEY: From this morning, it's a growing field.

ZACHARY MCCARTY: Of the profession and because they're being regulated, they realize Blue Button does not work. And they released they're going to do a new Blue Button to try to get people to do their electronic health records. They say that we need to work to reduce that administrative burden so doctors can get back to doing what we do best, which is caring for our patients. It's called #patientsoverpaperwork.

BETH DELANEY: And Dr. Chaum.

EDWARD CHAUM: So, I think what we're seeing here is growing pains. Clearly medicine is changing. It's changing in front of us. It's changing under our feet. And figuring out the best way through to meet the needs of the consumers and also the needs of our own practices and our livelihoods and our frame of mind, if you will, are issues that we need to come to terms with. And we need to find a common ground to meet all of those obligations.

And I think as we grow into an electronic health record era, and that becomes part of our daily medical practice, that a lot of these growing pain issues are going to be issues of the past.

BETH DELANEY: Great. And I'd like to just remind everybody about the comment period. There's another month. Please send us your suggestions, some feedback on what our panelists have been talking about. We really want this to be an ongoing dialogue. And I want to end with, please pay your lunch bill.

DAN GILMAN: I used cash.

[SIDE CONVERSATIONS]

[JAZZ MUSIC]